The impact of mobile mindfulness meditation on mental health and well-being in university students

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A thesis

submitted in fulfilment

of the requirements for the degree of

Doctor of Philosophy (Psychology and Psychological Medicine)

by

Jayde Ana Michelle Flett

University of Otago

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Mindfulness meditation is a common psychotherapy informed by Buddhist mindfulness that is gaining traction outside of the clinic. One area that is particularly popular is *mobile* mindfulness meditation, the use of applications (apps) to deliver mindfulness. Given the relative newness of these apps and the high turnover rate of app technology, few studies have rigorously examined the effectiveness of mindfulness meditation apps for improving mental health. Thus, in a series of pragmatic, randomised, controlled trials, I investigated the effects of mindfulness meditation apps on university students' mental health.

In this thesis I report the effects of Study 1, a randomised, controlled trial examining the effect of app-based mindfulness meditation on mental health and adjustment to college life in a convenience sample of undergraduate psychology students (Study 1). Here, I found that app-based mindfulness was associated with small but significant improvements in a range of mental health and well-being outcomes. I also found that there were app-specific effects which suggest that not all mindfulness apps are created equally.

Study 1 provided the justification for Studies 2 and 3, where I investigated the effects of app-based mindfulness meditation on mental health in two targeted populations: a sample of clinically distressed university students who were seeking help through the university's Counselling Service (Study 2), and a sample of incoming first-year university students living in one of two residential colleges (Study 3). In these studies, I identified barriers to implementation in complex contexts (Study 2) and that the transition to university (during the first semester of the first year of university) is an optimal time to intervene with incoming university students (Study 3). I took a pragmatic approach to effectiveness trials in all of the

studies included in this thesis; that is, across all three trials I prioritised establishing the degree of effectiveness of mobile mindfulness meditation apps when they were used by a diverse population in a naturalistic setting, and where adherence is gently encouraged but not enforced. In doing so, I have contributed to the growing evidence of effectiveness for mobile MBI in real-world settings.

Although we may think that the only way to use technology mindfully is to turn it all off, in this thesis I demonstrate that mobile mindfulness meditation can help improve university students' mental health. Importantly, mobile mindfulness meditation was most effective among those who continued to use the app frequently. Identifying the factors that encourage sustained usage should be a priority for future research so that mindfulness app users can reap the rewards.

Keywords:

mindfulness, mobile health, young-adults, well-being, focus groups, semi-structured interviews, ecological momentary interventions, mHealth, randomised controlled trial, mental health

List of abbreviations:

ACT = Acceptance and Commitment Therapy
ANZCTR = Australia and New Zealand Clinical Trial Registry
BDI = Beck Depression Inventory
CES-D = Centre for Epidemiological Studies Depression Scale
DBT = Dialectical Behavioural Therapy
FS = Flourishing Scale
HADS = Hospital Anxiety and Depression Scale
HADS-A = Hospital Anxiety and Depression Scale – Anxiety Subscale
HADS-D = Hospital Anxiety and Depression Scale – Depression Subscale
K6 or K10 = Kessler Psychological Distress Scales
MBI = Mindfulness-based intervention
MBCT = Mindfulness-based cognitive therapy
MBSR = Mindfulness-based stress reduction
NA = negative affect
NIH = National Institute of Health (USA)
NHS = National Health Service (UK)
OR = odds ratio
PA = positive affect
PHQ-9 = Patient Health Questionnaire 9
pRCT = pragmatic randomised controlled trial
PSS = Perceived Stress Scale
RCT = randomised controlled trial
RwCT = randomised waitlist-controlled trial
SD = standard deviation
SE = standard error
SHS = Student Health Services
SMC = Standardized mean change
SMD = Standardized mean difference

Acknowledgements

This thesis has been and will likely only be read by a select few: my supervisory dream-team, my extremely generous mother-in-law, and the (fingers-crossed) judicious examiners. Thank you for taking the time out of your busy lives to read the culmination of several years of work. I hope you enjoy it. Good luck and remember to breathe, ha!

This body of research makes up a story of works that follow a similar theme. They are not the only work that has taken place over the last five years, merely the ones that fit into this story. A great deal of effort towards these projects, and others, has been contributed by a number of people whose names don't make it onto the cover of this behemoth. For those that have helped me along the way, whether in terms of research support or as participants involved in this research, I give you my sincerest thanks. A global thanks isn't really isn't enough, so a brief acknowledgement will be made at the end of each study chapter acknowledging those who put in a great deal of time and resources to see these projects through. But there are a select number of people that I would like to thank in greater detail.

First, I would like to give special thanks to my supervisors Professor Harlene Hayne, Associate Professor Tamlin Conner, and Dr Tess Patterson – a group of strong, independent, clever women who have formed a protective layer around me, pushing me to become a better academic and person over the last few years. It is not in jest that I call you the dream-team. I couldn't fathom what a wealth of knowledge, support, and faith you would all be; I am very fortunate to have had the opportunity to grow under your tutelage.

Second, I would like to thank the University of Otago for giving me the opportunity to carry out this PhD research and for providing financial assistance along the way. Additionally, to the Alumni of Otago in America, who supported my travel and further education in the United States of America. I would like to thank Dr. Kim Ma'ia'i for his support and advice as my Advisor. I would also like to thank Dr. Gareth Treharne and Dr. Damian Scarf for their

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Third, to my lab members, but especially to Ben Riordan and Roisin Hegarty. Ben, you have been my greatest collaborator, a best friend, and a great driving point. Without the ability to bounce ideas off you, I would probably still be writing this damn thing. I expect we have many years ahead of us to continue collaborating on projects. Roisin, without our lunchdates, your positive and pragmatic attitude, and your qualitative research experience, I would have never completed this thesis.

And fourth, to my family and friends. To my parents and siblings, thank you for always believing in me and for always letting me take my own path. To my grandparents, for helping me keep my eye on the prize. To Imogen, for her keen eye, unwavering enthusiasm, and for Shannon. To my friends who have put up with my semi-regular existential crises. And finally to Tod. Thanks for joining me on this ‘wild ride’. You have been by my side since the very start. I am so glad that you didn’t let me scare you away at the get go. I hope we can have many more adventures together.

PUBLICATIONS AND PRESENTATIONS

Publications featuring in this thesis

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Flett, J. A. M., Fletcher, B. D., Riordan, B. C., Patterson, T., Hayne, H., & Conner, T. S. (2019). The peril of self-reported adherence in digital interventions: a brief example. *Internet Interventions*. Online First.	Chapter 3: Supplement 5	Lead author, co-designed study, analysed the data; wrote publication.
Flett, J. A. M., Conner, T. S., Riordan, B. C., Patterson, T., & Hayne, H (2020). App-based mindfulness meditation for psychological distress and adjustment to college in incoming university students: A pragmatic, randomised, waitlist-controlled trial. *Psychology & Health*, 1-26.	Chapter 4	Lead author, co-designed study, ran the study, led data collection, analysed the data; wrote publication.

Conference proceedings resulting from this thesis

Flett, J. A. M., Hayne, H., Riordan, B. C., & Conner, T. S. (2015, September). *But is there an app for that? The potential for mHealth uptake in student populations.* Poster presented at the New Zealand Public Health Association Conference, Dunedin, New Zealand.

Flett, J. A. M., Hayne, H., Riordan, B. C., Thompson, L., & Conner, T. S. (2016, September). *Mobile mindfulness meditation: Benefits and barriers to uptake.* Oral presentation at the New Zealand Psychological Society Conference, Wellington, New Zealand.

Flett, J. A. M., Hayne, H., Riordan, B. C., Thompson, L. M., & Conner, T. S. (2016, November). *Mobile mindfulness meditation: Using apps to cultivate well-being.* Oral presentation at Kiwi Cognition and Memory, Dunedin, New Zealand.

Flett, J. A. M., Hayne, H., Riordan, B. C., Thompson, L. M. & Conner, T. S. (2017, May). *Mindfulness meditation and mental health: "Is there an app for that?"* Poster presented at the Association for Psychological Science Conference, Boston, MA, USA.

Flett, J. A. M., Hayne, H., Riordan, B. C., Patterson, T., & Conner, T. C. (2018, May). *Mobile mindfulness meditation: Using apps to try to cultivate mental health and well-being.* Oral presentation at the University of Otago, School of Medicine Hot Health Series, Dunedin, New Zealand. ***Invited Speaker***

Fletcher, B. D., **Flett, J. A. M.,** Rarm, I., & Conner, T. S. (2019, February). *Predictors of mindfulness meditation app adherence for improved mental health.* Poster presented at the International Society for Research on Internet Interventions Conference, Auckland, New Zealand. ***Poster selected for a poster highlighting session***

Flett, J. A. M., Hayne, H., Conner, T. S., Ma'ia'i, K., & Patterson, T. (2019, February). *With a complex population and a complex problem, remember to 'Keep it [the research design] Simple, Stupid!'.* Oral presentation at the International Society for Research on Internet Interventions

Conference, Auckland, New Zealand.

Flett, J. A. M., Hayne, H., Riley, J., Fletcher, B. D., Riordan, B. C., & Conner, T. S. (2019, February). *Mobile mindfulness meditation: Can apps deliver mental health benefits?* Oral presentation at the International Society for Research on Internet Interventions Conference, Auckland, New Zealand.

Flett, J. A. M., Fletcher, B. D., Riordan, B. C., Patterson, T., Hayne, H., & Conner, T. S. (2020, January). *The peril of self reported adherence in digital interventions.* Oral presentation at the Society for Ambulatory Assessment Conference, Melbourne, Australia.

Additional publications

(not featuring in this thesis, but from my time as a PhD student)

Beres, M., Treharne, G. J., Stewart, K., Flett, J. A. M., Rahman, M., & Lillis, D. (In Press). A mixed-methods pilot study of the EAAA rape resistance programme at a New Zealand university. *Women's Studies Journal.*	---	Led data collection, co-wrote publication.
Riordan, B. C., **Flett, J. A. M.,** Conner, T. S., & Scarf, D. (Online first). The Fear of Missing Out (FoMO) and event-specific drinking: The relationship between FoMO and alcohol use, harm, and Blood Alcohol Concentration during large social events. *Current Psychology.* doi: 10.1007/s12144-019-00318-6	---	Co-designed study, contributed to data collection; co-wrote publication.
Willroth, E. C., **Flett, J. A. M.,** & Mauss, I. B. (In press). Emotion differentiation and depressive symptoms: Negative, positive, and within-emotion-category impairments. *Journal of Personality*. doi: 10.1111/jopy.12475	---	Co-designed study, contributed to data analysis; co-wrote publication.
Conner, T. S., McFarlane, K. G., Choukri, M., Riordan, B. C., **Flett, J. A. M.,** Phipps-Green, M., Topless, R., Merriman, M., & Merriman. T. R. (2018). The oxytocin receptor gene (OXTR) variant rs53576 is not related to emotional traits or states in young adults. *Frontiers in Psychology, 9,* 2548. doi: 10.3389/fpsyg.2018.02548	---	Contributed to data collection; co-wrote publication.
Riordan, B. C., †Cody, L., †**Flett, J. A. M.,** Conner, T. S., Hunter J., & Scarf, D. (2018). The development of a single item FoMO (Fear of Missing Out) scale. († Authors contributed equally). *Current Psychology.* doi: 10.1007/s12144-018-9824-8	---	Co-conceived the study, contributed to data collection; co-wrote publication.
Riordan, B. C., Conner, T. S., **Flett, J. A. M.,** Droste, N., Cody L., Brookie. K., Riordan, J. K., & Scarf, D. (2018). An intercept study to measure the extent to which New Zealand university students pre-game. *Australian and New Zealand Journal of Public Health, 42*, 30-34. doi: 10.1111/1753-6405.12754	---	Co-conceived the study, contributed to data collection; co-wrote publication.

Riordan, B. C., Conner, T. S., Thrul, J., **Flett, J. A. M.,** Carey, K. B., & Scarf, D. (2018). Just a first-year thing? The relations between drinking during Orientation Week and subsequent academic year drinking across class years. *Journal of Substance Use and Misuse.* doi: 10.1080/10826084.2017.1415354	---	Contributed to data collection; co-wrote publication.
Conner, T. S., Thompson, L. M., Knight, R., **Flett, J. A. M.,** Richardson, A. C., & Brookie, K. L. (2017). The role of personality traits in young adult fruit and vegetable consumption. *Frontiers in Psychology, 8,* 119. doi: 10.3389/fpsyg.2017.00119	---	Managed data collection; co-wrote publication.
Flett, J. A. M., Lie, C., Riordan, B. C., Conner, T. S., & Hayne, H. (2017). Sharpen those pencils: Preliminary evidence that adult colouring reduces depressive symptoms and anxiety. *Creativity Research Journal, 29*(4), 409-416. doi: 10.1080/10400419.2017.1376505	---	Lead author, co-designed study, ran the study, led data collection, analysed the data; wrote publication.
Riordan, B. C., Conner, T. S., **Flett, J. A. M.,** & Scarf, D. (2017). A text message intervention to reduce first year university students' alcohol use: A pilot experimental study. *Digital Health, 3,* 1-10. doi: 10.1177/2055207617707627	---	Contributed to data collection; co-wrote publication.
Gauld, R., **Flett, J. A. M.,** McComb, S., & Gray, A. (2016). How responsive are government agencies when contacted by email? Findings from a longitudinal study in Australia and New Zealand. *Government Information Quarterly, 33*(2), 283-290. doi: 10.1016/j.giq.2016.03.004	---	Led data collection, co-wrote publication.
Riordan, B. C., Scarf, D., Moradi, S., **Flett, J. A. M.,** Carey, K. B., & Conner, T. S. (2017). The accuracy and promise of personal breathalysers for research: Steps towards a cost-effective objective measure of alcohol use? *Digital Health, 3,* 1-5. doi: 10.1177/2055207617746752	---	Co-conceived the study, contributed to data collection; co-wrote publication.
Riordan, B. C., **Flett, J. A. M.,** Lam, T., Conner, T. S., & Scarf, D. (2016). The Jekyll and Hyde of our drinking: Event specific drinking, intervention, and prevention. In W. Gutierrez (Ed.), *Alcohol Consumption: Patterns, Influences and Health Effects* (pp. 129-166). Nova Science Publishers, Inc: Hauppauge, NY.	---	Co-wrote publication.
Riordan, B. C., **Flett, J. A. M.,** Conner, T. S., & Scarf, D. (2016). Text message interventions for alcohol use: Current research and future directions. In Winston Gutierrez (Ed.), *Alcohol Consumption: Patterns, Influences and Health Effects* (pp. 185-192). Nova Science Publishers, Inc: Hauppauge, NY.	---	Co-wrote publication.

Riordan, B. C., **Flett, J. A. M.,** Hunter, J., Scarf, D., & Conner, T. S. (2015). Fear of Missing Out (FoMO): The relationship between FoMO and alcohol use and consequences in college students. *Annals of Neuroscience and Psychology, 2*, 1-7. Retrieved from http://www.vipoa.org/neuropsychol/2/7	---	Co-conceived the study, contributed to data collection; co-wrote publication.
Riordan, B. C., Conner, T. S., **Flett, J. A. M.,** & Scarf, D. (2015). Out of touch? The shortcomings of New Zealand's amended Sale and Supply of Alcohol Act (2012) for the Rugby World Cup (2015). *New Zealand Medical Journal, 128*(1422), 73-74.	---	Co-wrote publication.
Riordan, B. C., Conner, T. S., **Flett, J. A. M.,** & Scarf, D. (2015). A brief Orientation Week intervention to reduce student alcohol use. *Journal of Studies on Alcohol and Drugs, 76*(4), 525-529. doi: 10.15288/jsad.2015.76.525	---	Contributed to data collection; co-wrote publication.
Polak, M. A., Richardson, A. C., **Flett, J. A. M.,** Brookie, K. L., & Conner, T. S. (2015). Measuring mood: Considerations and innovations for nutrition science. In T. Best & L. Dye (Eds.), *Nutrition for brain health and cognitive performance.* (pp. 95-122). CRC Press: Boca Raton, FL.	---	Co-wrote publication.

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A Personal Disclosure

It is inevitable that mindfulness and other practices adopted from Buddhism will find new applications in the modern West, where worldviews and lifestyles are so different from those of southern and eastern Asia. If such practices benefit those who do not accept the full framework of Buddhist teaching, I see no reason to grudge them the right to take what they need. To the contrary, I feel that those who adapt the Dhamma to these new purposes are to be admired for their pioneering courage and insight. As long as they act with prudence and a compassionate intent, let them make use of the Dhamma in any way they can to help others.

At the same time, I also believe that it is our responsibility, as heirs of the Dhamma, to remind such experimenters that they have entered a sanctuary deemed sacred by Buddhists. Thus, respectful towards their sources, they should pursue their investigations with humility and gratitude. They should recognize that while the Dhamma bids everyone come and take what they need, they are drawing from an ancient well of sacred wisdom that has nourished countless spirits through the centuries and whose waters still retain their potency for those who drink from them today.

Bhikkhu Bodhi of the Chuang Yen Monastery (2011, p. 36)

At the outset of this thesis I knew nothing about mindfulness, meditation, or the deep and rich historical and cultural background from which they came. In this thesis I have aimed to provide a respectful account of this rich history. While I have spent the last five years researching the effects of brief, mobile, secular, mindfulness meditation on mental health in young adults, I have done so in good faith. I am respectful and grateful for this knowledge.

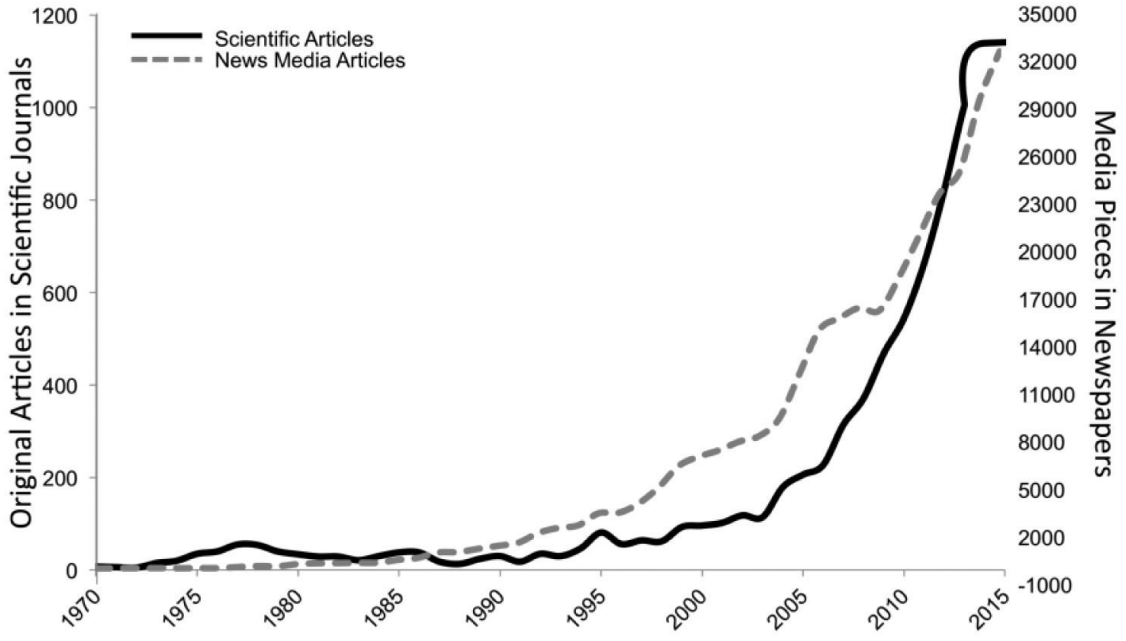
As someone who is not a Buddhist, a philosopher, or a theologian, I have relied heavily on secondary sources on Buddhist thought and practices in order to place this work in context. I have done so to the best of my abilities but acknowledge that there will be areas where I have likely made errors. Please forgive me; these errors are unintentional.

Finally, this thesis represents many years of work, and in it I hope you find an intellectually honest but challenging account of not only the existing research but also the research process. At the outset, I was sceptical of mindfulness but I didn't know why. I suppose that any one thing presented as a panacea doesn't sit well with me. Although I read the supporting literature and took the researchers at their word, I now have a more ruthless eye for intervention methodology and my scepticism is not necessarily with mindfulness itself, but with the idea of a panacea.

CHAPTER 1: LITERATURE REVIEW

The role of mindfulness meditation in mental health

Meditation and mindfulness are currently experiencing a renaissance. In 2014, "how to meditate" was the second highest 'how to' Google search term in Aotearoa New Zealand and the fourth highest in the UK (Google, 2014). In 2017, 14.2% of American adults reported that they meditate, a three-fold increase from 2012 (Clarke, Barnes, Black, Stussman, & Nahin, 2018). Likewise, there was a ten-fold increase in the use of meditation by children from 0.6% to 5.4% between 2012 and 2017 (Black, Barnes, Clarke, Stussman, & Nahin, 2018). As mindfulness and mindfulness meditation have become part of the popular zeitgeist, research on the impact of these practices has also blossomed. For example, two articles published in 1969 constituted two-thirds of the English-language experimental work on meditation (Shapiro, 1994) but by 2015, this number had skyrocketed to over 1000 scientific publications (see Figure 1.1., reproduced from p.2, Van Dam et al., 2017).



Reproduced Figure. 1.1. **Scientific and news media articles on mindfulness and/or meditation by year from 1970 to 2015. Empirical scientific articles (black line) with the term mindfulness or meditation in the abstract, title, or keywords, published between 1970 and 2015 were searched using Scopus. Media pieces (dashed gray line) with the term mindfulness or meditation, published in newspapers, using a similarity filter to minimize double-counting, published between 1970 and 2015 were searched using LexisNexis.** ***(Van Dam et al., 2017, p. 2)*****.**

Despite enjoying newfound popularity, mindfulness is challenging to define (R. A. Baer, 2011; Van Dam et al., 2017). The term is used to refer to several related concepts: mindfulness is a state, a trait, and a practice. Within contemporary psychotherapeutic research, a commonly used definition is that mindfulness is "paying attention in a particular way: on purpose, in the present moment, and nonjudgmentally" (Kabat-Zinn, 2013, p. 4). A principal means of practising mindfulness is through meditation.

To better place this work in context, in Chapter 1, I will provide a brief history of mindfulness and mindfulness meditation starting with an abridged historical timeline, before discussing contemporary applications of mindfulness and mindfulness meditation. I will then review broader meta-analytic evidence linking mindfulness meditation to mental health[1] with a brief overview of some of the key empirical research. Next, I will discuss the outstanding challenges facing mindfulness intervention research. Finally, I will conclude by summarising the nascent research on *mobile* mindfulness meditation, that is, the use of mobile phones to deliver mindfulness meditation as a mental health intervention. In doing so, I will provide a justification for the three empirical studies included in this thesis.

[1] Here, *mental health* describes both negative (e.g., depressive symptoms) and positive (e.g., resilience) psychological factors that contribute to an individual's overall mental state. *Ill-being* refers to negative components that contribute to mental health (e.g., depression, anxiety, stress); while *well-being* refers to the positive components that contribute to mental health (e.g., resilience, flourishing, and trait mindfulness).

1.1. A Brief History of Mindfulness: An Origins Story

Mindfulness has a long spiritual past and a short secular history

(Monteiro, Musten, & Compson, 2015, p. 2)

The origins of Mindfulness are generally attributed to Buddhism, but contemplative practices like mindfulness meditation have been found in many religions including Christianity (Hesychasm and the Rosary), Judaism (Kabbalah), Islam (Tafakkur and Sufism), and Hinduism (Bhakti), many of which predate Buddhism (Khong, 2009; Lutkajtis, 2019). Theological scholars contest the authenticity and interpretations of most religious texts, and early Buddhist literature is no exception (see: Sujato, 2005). Nevertheless, most contemporary, secular, and clinical applications of mindfulness meditation have stemmed from a Buddhist framework of mindfulness (Kabat-Zinn, 2011) which has its roots in meditation. For this reason, in the following simplistic, abridged, and likely contestable timeline of mindfulness, I focus primarily on the Buddhist antecedents of meditation. Important periods of the timeline are underlined.[2]

An Abridged Timeline

Pre-mindfulness

50000–35000 BCE Rossano (2007) controversially argues that meditation-like and shamanistic rituals enhanced the working memory of our Homo sapiens ancestors. Over time these meditation-like practices were argued to have caused gene mutations which favoured enhanced memory and ultimately gave Homo sapiens a Baldwinian[3] evolutionary advantage over Neanderthals.

3000–1900 BCE Meditation is depicted in art from the Indus Valley Civilization in what is now India and Pakistan (Bryant & Patañjali, 2009). In Figure 1.2.,

[2] There are several schools of Buddhism: the two most prominent are Theravāda and Mahāyāna. Theravāda predominantly uses the Pāli language; Māhāyāna uses the Sanskrit language.
As someone who is not Buddhist, nor a trained theologian and historian, it is beyond the scope of this thesis to speculate on the authenticity or to provide a critical interpretation of the events presented in this timeline. Instead I have simply listed them in order with a brief description as provided in the cited source. For this reason, I have used Sanskrit and Pāli terms interchangeably. For terms that are not commonplace, I have attempted to provide a commonly understood term in parentheses.

[3] Baldwinian is not to be confused with Darwinian theory or Lamarckism. Baldwinian evolution describes how "an organism's ability to learn new behaviours (e.g. to acclimatise to a new stressor) will affect its reproductive success and will therefore have an effect on the genetic makeup of its species through natural selection." (*Baldwin effect*, n.d.).

although some contest the meditation interpretation (e.g., McEvilley, 1981), a steatite seal depicts a person seated in a meditative posture (Marshall, 2004).

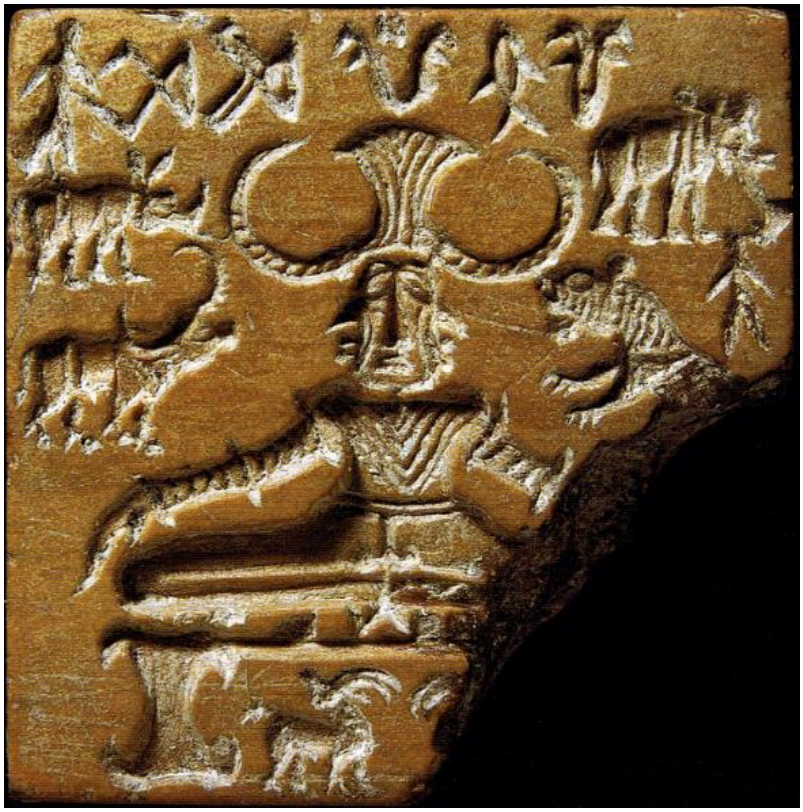


Figure 1.2. **Pashupati seal interpreted as sitting in a meditative posture. (source: *(*Pashupati seal*, n.d.)*.**

1400–400 BCE The earliest documentation of meditation is recorded in the *Vedas*, the oldest Hindu scripture detailing Hindu wisdom and knowledge. Orthodox Indian theologians believe the Vedas to contain revelations seen by ancient sages following intense meditation. The Vedas existed as an oral history long before they entered the written record.

500 BCE Siddhartha Gautama founded Buddhism. Early Buddhist texts present conflicting evidence about Gautama's early life, but scholars generally agree that he went on a quest to end the repeated suffering of humanity resulting from endless rebirth (reincarnation). In doing so, he gained insight into the workings of karma, attained enlightenment, and was recognised as a fully enlightened Buddha, going on to be commonly referred to as *the Buddha* ("the one who has understood" Johansson, 1969, p. 21). The Buddha spent the rest of his life teaching the *dharma* (universal principles) of Buddhism. The Buddha's teachings were shared through oral histories for the first four centuries (Bodhi, 2011). To facilitate the retention of these teachings, they were compressed into simple and repetitive formulas to allow each generation

of followers to commit the lessons to memory (Bodhi, 2011). The cornerstone of Buddha's principles are the *Four Noble Truths*:

1) ***Dukkha***[4]: The truth of suffering.
2) ***Samudāya***: The truth of the origin of suffering.
3) ***Nirodha***: The truth of the cessation of suffering.
4) ***Marga***: The truth of the path to the cessation of suffering.

In the *Kālāma Sutta* (from the Pāli Canon of the Theravāda branch), the Buddha explicitly presents his dharma as a testable hypothesis (Batchelor, 2011; Maex, 2011). Further, some have used the Four Noble Truths to make the analogy of the Buddha as a physician (Nimalasuria, 1980; Olendzki, 2005). In the first Noble Truth he diagnoses the problem. In the second he identifies its cause. In the third he realises that there is a cure. And in the fourth he recommends a prescription to alleviate this suffering ('The Four Noble Truths', 2009). This prescription is better known as *the Eightfold Path* (or the Middle Way), a set of principles to end suffering. It is through the fourth Noble Truth that we come closer to the contemporary understanding of mindfulness, the seventh path of the Eightfold Path. The relations between these principles are demonstrated most simply in Figure 1.3.

In the Eightfold Path there are eight principles which, if followed, should alleviate suffering. Importantly, the eight principles are not a simple sequence; they should be practised in parallel and are often pictorially represented as the wheel of a ship (Bodhi, 2011; Maex, 2011; Nimalasuria, 1980). The principles of the Eightfold Path[5] are:

1) ***Sammā***[6] ***ditthi*** **- Right Understanding**, accepting Buddha's teachings. But, note the intention is not for the Dharma to be followed blindly.
2) ***Sammā sañkappa*** **- Right Intention,** making a commitment to cultivate the right attitudes.
3) ***Sammā vācā*** **- Right Speech**, speaking truthfully, avoiding slander and abuse

[4] Less commonly, some Buddhist scholars translate *dukkha* to mean stress (see: Kabat-Zinn, 2011).
[5] The description of these principles was adapted from ('The Four Noble Truths', 2009)
[6] The term sammā is translated to mean "right" but should be interpreted more generally as "appropriate" (Olendzki, 2005).

4) ***Sammā kammanta* - Right Action**, behaving peacefully; refraining from lying, stealing, killing, and overindulgence
5) ***Sammā ājīva* - Right Livelihood**, avoiding making a living in ways that are exploitative or cause harm
6) ***Sammā vāyāma* – Right Effort**[7], cultivating positive states of mind, freeing oneself from evil or unwholesome states and preventing their return
7) ***Sammā sati* – Right Mindfulness**[8], developing awareness of the body, sensations, feelings, and states of mind
8) ***Sammā samādhi* - Right Concentration**, developing the mental focus necessary for awareness.

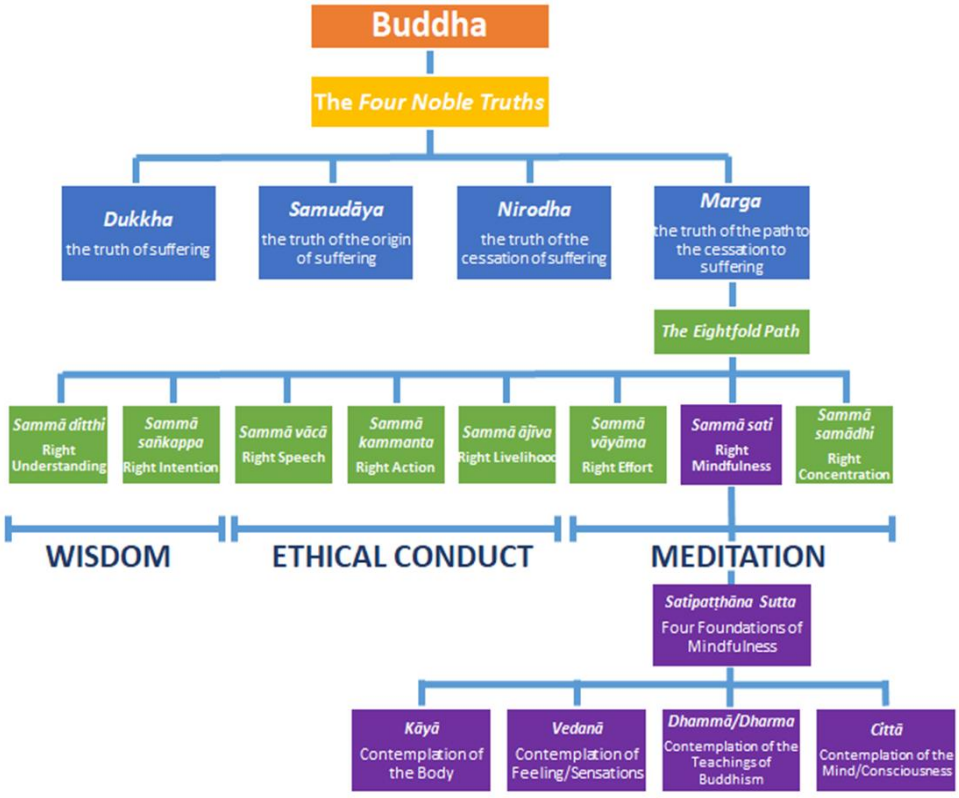


Figure 1.3. A simplified 'family tree' of Buddhist principles.

[7] Batchelor (2011), describes how Right Effort is developed with the *'Four Great Efforts'* and that Mindfulness-Based Cognitive Therapy is in accordance with the four great efforts:

1. To cultivate conditions so that negative states that have not arisen do not arise.
2. To let go of negative states once they have arisen.
3. To cultivate the conditions that enable positive states to arise.
4. To sustain positive states once they have arisen.

[8] *Sati* – mindfulness, is also one of the Seven Factors of Enlightenment (*Bojjhanga*) alongside: Keen investigation of the dhamma-*dhammavicaya*, Energy-*viriya*, Rapture or happiness-*piti*, Calm-*passaddhi*, Concentration-*samadhi*, and Equanimity-*upekkha*.(Thera, 2006).

To facilitate memory of the Eightfold Path, the eight principles are often collapsed under three categories: wisdom, ethical conduct, and meditation[9].

1) **Wisdom** – sometimes termed ***prajñā*** understanding – can be thought of as the gate to the *Eightfold Path* (Maex, 2011). For example, Maex (psychiatrist and Zen practitioner), maintains that help seekers will not engage in secular and psychotherapeutic mindfulness (e.g., MBSR or MBCT) if they do not understand or trust *why* they should try mindfulness and how it might be helpful to them (Maex, 2011).

2) **Ethical conduct** – sometimes termed ***sīla*** virtue – is the category that secular and clinical mindfulness struggles with (R. Baer, 2015) because some argue that science should be devoid of ethical values. But the idea that science or clinical medicine is devoid of ethical values is at odds with the Hippocratic Oath, the cornerstone of medical ethics.

3) **Meditation** is the final super-ordinate category and includes the seventh path, mindfulness.[10]

Although there are many forms of meditation, the two most prevalent types (found in the earliest teachings of the Buddha) are:

1. ***Śamatha*** or concentration meditation (Olendzki, 2005; also described as: calmness, stability and concentration, Batchelor, 2011; stopping and calming, Maex, 2011). In śamatha an object serves as a focal point of attention. As distracting thoughts or sensations arise, attention is purposely brought back to the primary focal point. When this focus is sustained it is thought to lead to stability, concentration, and tranquillity. A simple example of śamatha is breathing meditation, where the meditator uses their breath as a key focal point; this is a form of sitting meditation described in further detail on page 16.

2. ***Vipassanā*** (insight, Batchelor, 2011; looking and seeing clearly, Maex, 2011; Mindfulness, Olendzki, 2005). In vipassanā, awareness is purposefully moved from one object to another as stimuli

[9] These three categories have been given different labels by different scholars (e.g., Maex, 2011: understanding, virtue, and meditation; ('The Four Noble Truths', 2009): wisdom, ethical conduct, meditation), but typically involve the same classification of principles.

[10] In addition to the Four Foundations of Mindfulness, there are several other limbs of key Buddhist principles that stem from meditation. One key set of meditation principles are the *Four Immeasurables* in which meditation is used to develop loving-kindness, compassion, appreciative joy and equanimity (Grossman & Van Dam, 2011). Loving kindness meditations are sometimes used in mindfulness based interventions.

present themselves. When this practice is sustained it is thought to lead to insight about the subjective construction of experience and provide insight into the three characteristics of existence: impermanence, suffering, and non-self. A simple example of vipassanā is a body scan meditation, where the meditator systematically focuses on parts of their body; this is described in further detail on page 16.

Vipassanā is often termed mindfulness meditation (e.g., Olendzki, 2005) but mindfulness training typically involves both śamatha and vipassanā-style meditation ('Types of meditation.', n.d.). The *Satipaṭṭhāna Sutta* – the Four Foundations of Mindfulness (Pāli Canon, Theravāda Buddhism., Bodhi, 2011; Olendzki, 2005; see Nyanasatta, 2013 for a full translation) describes the building blocks necessary to develop mindfulness. The Four Foundations are:

1. ***Kāyā*** **- Contemplation of body.** Involves deliberate and mindful breathing, bodily postures, and mindful comprehension; reflection on the body, the elements, and death.
2. ***Vedanā*** **- Contemplation of feelings.** Involves focusing on the present moment and being aware of your feelings and the valence of these feelings (pleasant, unpleasant, neutral).
3. ***Cittā*** **- Contemplation of mind.** Involves shifting attention from bodily sensations and feelings. Directing awareness to the quality of the mind as it arises and passes by, moment by moment.
4. ***Dhammā/Dharma*** **- Contemplation of the teachings of the Buddha.** Involves deliberating on Buddhist dharma (e.g., the four noble truths; ('Satipatthana Sutta', n.d.).

In short, meditation is an exercise that enables us to see how our mind works and to learn how to shift from reacting, to mindfully holding and responding appropriately to whatever holds our attention (Maex, 2011). By meditating on our body, feelings and sensations, the mind and consciousness, and the teachings of the Buddha, it is said that we ultimately develop mindfulness (Batchelor, 2011).

500–400 BCE In the same century as the Buddha, three other religions that use a form of meditation, were founded. They are: Jainism in India (founded by Mahavira), Taoism in China (founded by Lao Tze) and Confucianism in China (founded by Confucius) ('The History of Meditation (A 5,000 Years Timeline)', n.d.).

Foundation of Buddhist Mindfulness

400–100 BCE The *Yoga Sutras of Patañjali* compiles 196 Indian sutras (rules or concise principles) on the theory and practice of yoga. One of the *Eight Limbs of Yoga* is *dhyana*, also known as meditation. Although mindfulness is not explicitly mentioned by Patañjali, many translations and commentaries interpret the sutras in relation to mindfulness (e.g., Bryant, 2015). These interpretations are unsurprising given that several of the 'limbs' overlap with key concepts involved in mindfulness meditation (e.g., *pranayama* – breath control: controlling the in- and out-breath; *pratyahara* – sensory inhibition or sense withdrawal: controlling the senses that bring attention into the outside world; and *dharana* – concentration: fixing attention to a selected inner object for the contemplative process) (Bryant, 2015).

400–200 BCE The poem, the *Bhagavad Gita*, describes the philosophy of yoga, meditation and spirituality (Violatti, 2013).

Popularisation of Buddhism in the US and Europe

327–325 BCE Alexander the Great's military exploits in India exposed Greek philosophers to Indian sages and yogis. Greek philosophers adopted meditative practices (e.g., *omphaloskepsis* or navel-gazing) to support their philosophical contemplation. Other later philosophers, *Philo* of Alexandria and *Plotinus*, developed additional meditation techniques ('The History of Meditation (A 5,000 Years Timeline)', n.d.).

500 AD Zen Buddhism is founded in Japan.

1800s AD In the late 1800s interest in mysticism and Eastern religions was common among the upper class (Gordon, 2009).

1860s–1890s AD Eastern spiritual leaders, including Swami Vivekananda (1863–1902), Zen roshi Soen Shaku (1860–1919) and Paramahansa Yogananda (1893–1952), visit the West and help popularise meditation (Lutkajtis, 2019).

1890 AD In the *Principles of Psychology* William James describes the importance of a contemplative mind and states, "The faculty of voluntarily bringing back a wandering attention, over and over again, is the very root of judgement, character, and will … But it is easier to define this ideal than to give practical directions for bringing it about." (James, 1890, p. 463).

1893 AD The Parliament of the World's Religions was held in Chicago and is considered a landmark even for the popularisation of meditation in the USA

and the "first time that Westerners on Western soil received Eastern spiritual teachings directly from Asian teachers" (Lutkajtis, 2019, p.193).

1922 AD Hermann Hesse's *Siddhartha,* a story of the Buddha's spiritual journey of self-discovery, was published in German. It was published in the US in 1951 and adapted to film in 1972.

1927 AD The *Tibetan Book of the Dead* was translated into English and contributed to the popularity of Tibetan Buddhism.

1931 AD In an early essay, Franz Alexander examined the relation between Freudian psychoanalysis and meditative states. This work was continued by Geraldine Coster (cited in (Surmitis, Fox, & Gutierrez, 2018).

1934 AD Carl Jung suggested that Zen Buddhism and psychotherapy share the common goal of alleviating human suffering and that the Zen teacher and the psychoanalyst performed the same role in helping the student/patient (Lutkajtis, 2019).

1950 AD Zen Buddhism popularised – termed the "Zen Boom" of the 50s – following the Korean War (1950–53) (Keng, Smoski, & Robins, 2011).

1958 AD Jack Kerouac's *The Dharma Bums* invited increased attention to Buddhism and curiosity about meditation and mindfulness (Haynes, 2005), although his portrayal is criticised by some as shallow. More recent understandings would likely deem his portrayal to be cultural appropriation (c.f. Surmitis, Fox, & Gutierrez, 2018).

1960–1970 AD Cheaper air travel facilitated the cultural exchange between teachers of Buddhism and disenfranchised young people in the USA (Bodhi, 2011).

1966 AD Famous Vietnamese Buddhist monk (*Bhikkhu*), Thích Nhất Hạnh, wrote to and then met with Martin Luther King Jr to urge him to publicly denounce the Vietnam war, which he went on to do the following year (see letter: Hanh, 1965).

1968 AD Popular band the Beatles spent 3 months in an ashram in India. The media coverage of their stay further popularised meditation (specifically Transcendental Meditation) in the USA (Chui, 2018).

1971 AD Early adaptations of meditation to clinical settings were influenced by Transcendental Meditation (TM) and were examined in experimental settings (Wallace, Benson, & Wilson, 1971). These studies formed the basis of

Benson's Relaxation Response (Benson, 1975), the understanding that the mental state achieved during meditation could help recovery from stress-related illness. This work was continued by Goleman and Schwartz (1976) and laid the foundation for future meditation applications and research (Kabat-Zinn, 2011).

1975 AD As depicted in Figure 1.4., TIME magazine cover featured Maharishi Mahes Yogi and the headline: "Meditation: The Answer to all Your Problems?"

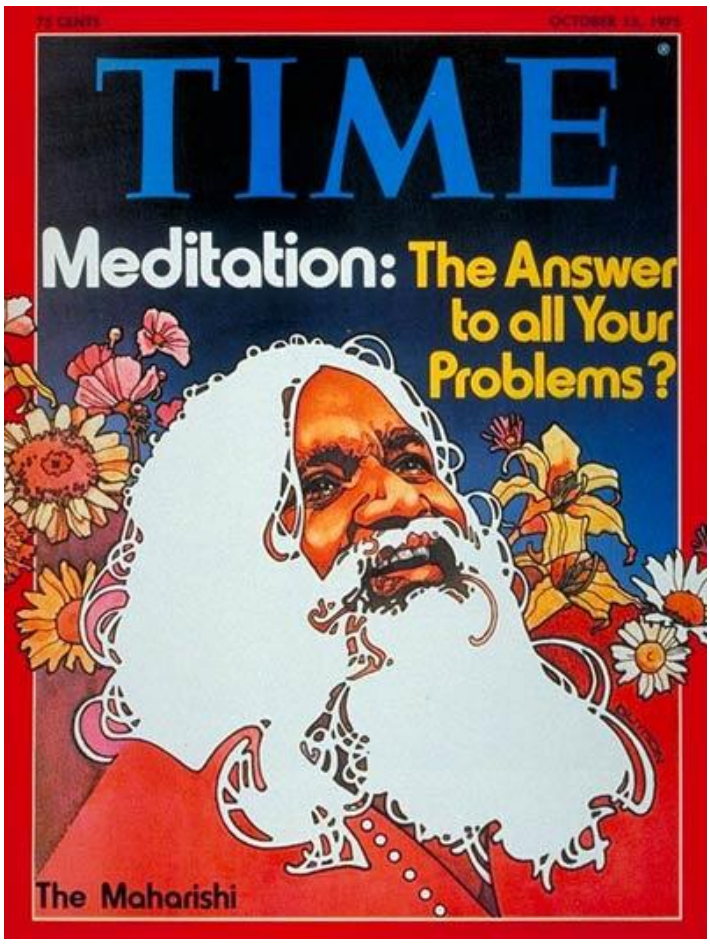


Figure 1.4. **TIME cover on 13 October 1975 features image of Maharishi Mahesh Yogi with the headline "Meditation: The Answer to all Your Problems?" *(*TIME cover: 'Meditation: The Answer to all Your Problems?', *1975)*.**

1975 AD Jon Kabat-Zinn – arguably the biggest influence on the clinical application of mindfulness – founded the Stress Reduction and Relaxation Program (later named the Stress Reduction Clinic) in September 1979. From this programme, Mindfulness-Based Stress Reduction (MBSR) was born (Kabat-Zinn, 2011). MBSR was the first formal, structured, mindfulness-based intervention to be used in clinical settings for clinical purposes. According to the Center for

Mindfulness, University of Massachusetts Medical School (Center for Mindfulness; UMASSMed, 2019), over 24,000 people have completed their official MBSR programme since its inception. MBSR has provided the inspiration and a framework for many mindfulness-based intervention offshoots including Mindfulness-Based Cognitive Therapy (MBCT: Segal, Williams, & Teasdale, 2013).

1980–2018 AD Annual publication on mindfulness-based research increases exponentially from *zero* publications in 1980 to at least 842 publications with mindfulness in their title in 2018 ("Mindfulness Journal Publications by Year, 1980–2018," ('Mindfulness Journal publications by year, 1980–2018', n.d.).

1987 AD The Mind and Life Institute began facilitating dialogue between the Dalai Lama, Buddhist scholars, philosophers, scientists, and clinicians (Williams & Kabat-Zinn, 2011).

2012 AD According to NIH statistics, 59 million Americans spent approximately $30 billion on complementary health approaches including meditation-related approaches in 2012 (Nahin, Barnes, & Stussman, 2016).

2014 AD TIME magazine continues to cover mindfulness

Figure 1.5. **Time cover on 3 February 2014: "The mindful revolution: The science of finding a focus in a stressed-out, multitasking culture".*(*TIME cover: 'The Mindful Revolution: The science of finding focus in a stress-out, multitasking culture'*, 2014)***

Commercialization of Mindfulness Meditation

2017 AD Calm, a popular mindfulness meditation app, wins iPhone App of the Year (Apple, 2017).

2018 AD Two mindfulness meditation apps, Headspace and Calm, rounded out first and second place in the top 10 self-care apps. Revenue in the top 10 self-care apps increased by 170% from the previous year and Headspace and Calm accounted for over 90% of the revenue (Quinn, 2018). Headspace and Calm have been downloaded over 38 million times and in June 2018 they both hit one million subscribers. Despite Headspace and Calm owning the market there are reportedly over two thousand meditation apps in the app stores (Schlagenhauf, 2018). Headspace Health, a subsidiary of Headspace, formalised their the intention of becoming the "world's first prescription meditation app" for chronic diseases with the approval of the FDA (Headspace, 2018).

2019 AD Calm valued at $1 billion USD (Bhardwaj, 2019).

1.2. Contemporary applications of mindfulness and mindfulness meditation[11]

The secular and clinical applications of mindfulness flourished in the late 1970s, in part due to Kabat-Zinn, but also due to globalisation, the post Korean-war popularisation of Buddhism in the 1950s (Tweed, 2013), and increased interest in Transcendental Meditation in the late 1960s (Chui, 2018). What began as clinical practitioners implementing their own experiences with Buddhist meditation in the clinic (Kabat-Zinn, 2011) ultimately grew into a broad practice sometimes referred to as the third-wave of psychotherapies (Hayes, Luoma, Bond, Masuda, & Lillis, 2006). According to Wielgosz, Goldberg, Kral, Dunne, and Davidson (2019), clinical interest in mindfulness meditation was propelled by a number of factors. For

[11] A parallel practice that shares the name mindfulness, but differs drastically from the style of mindfulness discussed throughout this thesis, is derived from Langer's (1989) cognitive model of mindfulness. Like Buddhist and Kabat-Zinn style mindfulness, Langerian mindfulness emphasises a flexible orientation to the present moment but also prioritises taking multiple perspectives, alertness to distinctions and context, and openness to novelty. Langerian interventions typically involve teaching participants to use multiple perspectives to look at information and situations from a new perspective to increase learning and creativity, and includes an external focus with goal-oriented problem solving. Langerian mindfulness is frequently used in art, business, and health contexts (Langer & Moldoveanu, 2000). Ellen Langer herself explicitly noted that her form of mindfulness is derived from a different historical and cultural background to the Buddhist and Kabat-Zinn style mindfulness discussed throughout this thesis, and has recommended caution when drawing links between the two forms. I do not address Langerian mindfulness any further; for a comprehensive review see: Langer & Moldoveanu (2000).

instance, the versatility of mindfulness to be applied to a broad range of conditions, the diversity of novel approaches that can be used with patients who may otherwise be unresponsive to treatment, the patient-led interest in the practice (thought to increase the likelihood of adherence and genuine engagement), and the fact that it can be extended to non-clinical populations with relative ease, have all been identified as key factors to mindfulness meditation's popularity in clinical settings (Wielgosz et al., 2019).

Early experimental work investigated the physiological reactions to Transcendental Meditation (see (Wallace et al., 1971); (Goleman & Schwartz, 1976) for published examples). For example, in a non-randomised pre-post study, experienced meditators and non-meditators were instructed to meditate with their eyes open or closed. They were then exposed to a stress induction exercise. Meditators and meditation was associated with lower self-reported anxiety and a faster recovery rate in terms of skin conductance and heart rate (Goleman & Schwartz, 1976). These studies laid the foundations for experimental interest in meditation and later interest in empirical evaluation of established clinical applications of mindfulness.

In the current section of this chapter, I will give a brief procedural description of formal mindfulness meditation exercises common to many Mindfulness-based interventions (MBIs) and describe structural processes that are common to most MBIs. Then, I will outline the four prominant therapies that use mindfulness as a key component of the therapy: Mindfulness-based Stress Reduction (MBSR), Mindfulness-based Cognitive Therapy (MBCT), Acceptance and Commitment Therapy (ACT), and Dialectical Behavioural Therapy (DBT). Examples of these well-established MBIs are described in Table 1.1.

1.2.1. Formal mindfulness meditation exercises common to many MBIs

The following exercises describe specific meditation practices common to many MBIs and to introductory mindfulness training. The formal exercises vary in effort (low, medium, high), orientation of attention (e.g., inward vs outward vs non-directional), spatial dynamic of attention (e.g., fixed [on the breath] vs moving [in a body scan]), the object of attention (e.g.,

fixed and specific [on the breath] vs fixed non-specific [on bodily sensations] vs no object), affective valence (e.g., positive vs neutral), and aperture of attention (e.g., narrow vs diffuse) (Van Dam et al., 2017). Most practices are conducted while seating in an upright position, although they can also be adapted to practise while walking, eating, and stretching. Finally, these exercises can be practised guided or unguided, although guided is typical during the introductory stages of mindfulness training to help facilitate the student through the practice. With practice, the student learns to implement these by themselves. Informal practice also includes bringing moment-to-moment awareness to ordinary daily activities including cooking and commuting. All of the practices described here sometimes go by other names, however, the foundational practices that are involved in most MBIs are: body scan, sitting meditation, and mindful movement. Example scripts for some of these practices have been kindly provided by Kent Smith and Janine Hills (care of Living Well, 2019) and can be found in the Supplement 1.1.

Body scan – this practice typically involves systematically and nonjudgmentally paying attention to parts of the body and associated bodily sensations. See Supplement 1.1.for example exercise. (See: Dreeben, Mamberg, & Salmon, 2013 for a historical overview and review of literature related to body scan.)

Sitting meditation – this practice typically involves paying attention to the breath. When thoughts arise or the attention wanders, the practice is to return the attention to a focal point such as the resting body, movement, or the breath (Salmon et al., 2004). See Supplement 1.1. for example exercise.

Mindful movement, yoga, or stretching meditation – this practice typically involves paying attention to the body during stretching exercises and stems from Hatha yoga (Goodman & Schorling, 2012).

Loving Kindness and Compassion meditations – these are not strictly mindfulness meditation specific practices but many MBIs incorporate them. Loving Kindness meditation typically involves systematically focusing on the image of different people (e.g., the self, a

good friend, a neutral person, a difficult person, all of the aforementioned people, and the universe) and directing feelings of positive energy initially toward the self and then extended toward a widening circle of others. (See: Hofmann, Grossman, & Hinton, 2011 for a historical overview and review of literature.) Compassion meditation involves a similar process but does not have to move systematically from internal (the self) to external (the universe). See Supplement 1.1. for an example of self-compassion mindfulness.

Noting – this practice typically involves identifying whatever thought or feeling is causing a distraction from immersion in the aforementioned practices. By noting the thought or feeling, the practitioner is more aware of it, is able to create space for the thought or feeling and able to practise letting it go (Headspace, n.d.). See Supplement 1.1. for two example exercises.

Reflection – this practice typically involves asking the self a question in the second person (e.g., "what are you most grateful for?") with the intention of focusing on the feelings that arise with focus on the question but not the thoughts (Headspace, n.d.).

Walking meditation – this practice typically involves paying attention to the process of walking, the movement of the body, and bodily sensations while walking. This practice can be extended to other everyday activities such as being mindful while washing the dishes, folding laundry, exercising, or cooking. See Supplement 1.1. for example exercise.

Mindful eating – this practice typically involves paying attention to cravings and physical cues (bodily sensations, colours, smells, sounds, textures, and tastes) during the process of eating. It involves slowly eating without distraction, listening to physical hunger cues (e.g., belly rumbling) and only eating when hungry, recognising hunger and non-hunger triggers, learning to cope with food-based guilt and anxiety, and noticing the effect of food on physical and mental states. See Supplement 1.1. for example exercise.

1.2.2. Structural processes common to most MBIs

Most manualised MBIs are structured group-based programmes with weekly classes held for eight weeks with optional follow up/maintenance classes over 6–12 months. Classes are led by a formal instructor and are typically 120–150 minutes long. Classes typically involve psychoeducation, formal meditation, and interaction between the instructor and the student exploring different aspects of mindfulness and meditative practice (this is called an 'inquiry'; Monteiro et al., 2015, Kabat-Zinn, 2011). MBIs generally involve some form of home practice, or homework. Home practice involves approximately 45 minutes of formal and 15 minutes of informal daily mindfulness practice. To generalise, MBIs involve approximately 16–32 hours of contact time (with the teacher) and 30–50 hours of home practice. Some MBIs include a day-long retreat (e.g., MBSR and MBCT). Most MBIs derived from MBSR will incorporate at least three formal meditation practices: body scan, sitting meditation, and stretching meditation.

Most established MBIs are goal-oriented – they aim to alleviate suffering, although for some this is a by-product of other goals (i.e., in ACT the goal is psychological flexibility; the alleviation of suffering is a by-product). Ultimately, MBIs aim to develop well-being, awareness (by becoming more aware of our thoughts, feelings, experiences), and acceptance (by not avoiding pain or suffering).

1.2.3. Common and Manualised MBIs

Below I describe the four most commonly used and most well-established MBIs and interventions incorporating mindfulness meditation, followed by a table outlining additional MBIs.

Mindfulness-based Stress Reduction (Kabat-Zinn, 1996) was the first systematic, formal, and secular mindfulness-based intervention to be used in a clinical setting. MBSR was influenced and informed by several Buddhist traditions including Theravada and Mahayana traditions (specifically, Soto and Rinzai Zen approaches), yogic traditions (Vedanta), early

research articulating dharma in plain language, and early research on the clinical application of meditation (Kabat-Zinn, 2011).

MBSR was originally developed to help people with chronic health problems deal with the psychological and emotional stress associated with their condition but has since been adapted to other disorders and is often labelled transdiagnostic (Crane et al., 2017). MBSR is an eight-week group programme that includes a day-long retreat. MBSR is delivered in a weekly class structure that includes psychoeducation, formal meditation and movement practices, and teacher-led discussion and inquiry; and daily home practices and exercises. MBSR maintains an experiential and educational format rather than therapeutic one and encourages modification of the programme where appropriate (Kabat-Zinn, 1996). Formal mindfulness exercises used in MBSR include: body scan, Hatha yoga, sitting meditation, and walking meditation; informal practices include: awareness during daily activities (e.g., eating), awareness of pleasant and unpleasant events, and awareness of breathing. The official Standards of Practice recommend that MBSR is not appropriate for some people. Notable exclusion criteria including those with active substance dependence (or recent recovery from substance dependence), and those with psychological issues (including suicidality, psychosis, PTSD, depression, and social anxiety); see the Standards of Practice [https://bit.ly/2LH10KJ] for a full list of exclusion criteria.

The MBSR course outline supplied by the Center for Mindfulness, University of Massachusetts Medical School (UMASSMed) is available here: https://bit.ly/2O6dtUd and Standards of Practice are available here: https://bit.ly/2LH10KJ

Mindfulness-based Cognitive Therapy (Segal, Williams, & Teasdale; 2002) is the most common adaptation of MBSR and is considered by some to be a third-wave CBT intervention (Hayes, Luoma, Bond, Masuda, & Lillis, 2006). MBCT is an 8-week group program for people with recurrent depression. In MBCT, students learn to recognise specific patterns of negative thinking (common to people with depression), with a goal of non-avoidance and intention and skilful responding. MBCT incorporates elements of cognitive

therapy but deviates from traditional cognitive therapy in that involves accepting thoughts and feelings without judgment rather than making any effort to evaluate or change their content. Like MBSR, it also incorporates a number of the basic formal and informal mindfulness meditation exercises. See Sipe and Eisendrath (2012) for an overview of the theory and practice of MBCT.

Acceptance and Commitment Therapy (Hayes, Strosahl, & Wilson, 1999) is a third-wave transdiagnostic cognitive behavioural therapy (CBT) intervention (Hayes et al., 2006) based on Relational Frame Theory (RFT; Hayes, Barnes-Holmes, & Roche, 2001). ACT is not based on MBSR. Unlike MBSR and MBCT, ACT is not a manualised intervention but instead is a set of evidence-based practices that are adapted and applied to patients/participants on an as-needed basis. The goal of ACT is to build psychological flexibility so that instead of avoiding suffering (such as difficult thoughts, feelings, and experiences), suffering is reperceived as harmless and transient. ACT has six core processes that promote the development of greater psychological flexibility: acceptance, cognitive defusion, being present, self as context, values, and a commitment to action. The processes can be categorised as mindfulness/acceptance processes (i.e., acceptance, cognitive defusion, being present, self as context) or commitment and behaviour change processes (i.e., being present, self as context, values, and a commitment to action). Each process has its own methodology, exercises, and homework (Hayes et al., 2006). Put simply, ACT uses behavioural activation strategies, acceptance and mindfulness processes, and commitment and values-guided exercises to build psychological flexibility.

Dialectical Behaviour Therapy (Linehan, 1993) is a third-wave CBT intervention that takes a cognitive, support-oriented, and collaborative approach to treat complex, difficult-to-treat mental health disorders. DBT was originally developed to treat chronically suicidal people but is more commonly used to treat borderline personality disorder and has been adapted to other "intractable" disorders (Dimeff & Linehan, 2001). It has four main training techniques: mindfulness, interpersonal effectiveness, distress tolerance, and emotion

regulation. DBT uses a combination of weekly individual psychotherapy sessions and group therapy skills sessions, with phone consultations and service provider consultations. DBT is dialectal in that it marries the idea of changing with the idea of acceptance (Dimeff, & Linehan, 2001). Like ACT, DBT is not based on MBSR.

Other Mindfulness-Based Interventions

The success of MBSR has been applied as a framework for a number of other mindfulness-based therapies with specific population or health targets. These emerging MBIs have limited evidence of efficacy (the effect under ideal conditions) and effectiveness (the effect under natural conditions) but present promising applications of the overarching theories to specific problems. Examples of emerging MBI are described in Table 1.1.

Table 1.1.

Description of mindfulness-based therapies.

Program	Common acronym	Reference	Length	Typical Format	Target	Mindfulness Components included	Distinguishing Characteristics	Selected Supporting Evidence
Well established MBIs								
Mindfulness-based Stress Reduction	MBSR	(Kabat-Zinn, 1982)	2–2.5hr/week 8 weeks + homework (45min formal practice, 15 min informal practice /6day/week) + full day retreat	Group	Originally chronic pain. Transdiagnostic	Body-scan, sitting meditation, Hatha yoga, diaphragmatic breathing, mindful eating, walking meditation	Original MBI	MA: (Khoury et al., 2013)
Mindfulness-based Cognitive Therapy	MBCT	(Segal et al., 2013)	8 week + homework (45min formal practice)	Group	People with recurrent depression	Sitting meditation, Hatha yoga	Cognitive therapy but accepting thoughts and feelings without judgment rather than making any effort to evaluate or change their content. Training about impermanence of thoughts to overcome rumination.	MA of individual patient data (Kuyken et al., 2016)
Well-established interventions incorporating mindfulness								
Acceptance and Commitment Therapy	ACT	(Hayes, Strosahl, & Wilson, 2009)	Varied	Individual	Transdiagnostic	Uses acceptance and mindfulness strategies to promote psychological flexibility and ultimately develop committed behavior change.	Psychological flexibility training. Identifying and committing to personal goals and values.	MA: (A-Tjak et al., 2015) MA, SR Web ACT: (Brown, Glendenning, Hoon, & John, 2016)
Dialectical Behavioural Therapy	DBT	(Linehan, 1993)	1–3.5hr/week + homework	4 modalities: Individual, group, telephone consultations, and therapist team meetings	Originally for people with borderline personality disorder and high suicide risk. Extended to other.	Mindfulness skills (what: observing, describing, and participating; how: non-judgmental, one-mindful, and effective)	Does not require formal meditation. Adaptive emotion regulation skills training. Contingency management and reduction of interfering emotions and cognitions	MA: (DeCou, Comtois, & Landes, 2019)

Program	Common acronym	Reference	Length	Typical Format	Target	Mindfulness Components included	Distinguishing Characteristics	Selected Supporting Evidence
Emerging MBI								
Mindfulness-based Relapse Prevention	MBRP	(Bowen, Chawla, & Marlatt, 2011)	2hr/week 8 week	Group	Substance use disorder	Guided meditation to enhance awareness and observation of the self. Body scan, loving-kindness, sitting meditation, mindful eating meditation (raisin exercise)	Cognitive and behavioral-based relapse prevention techniques and coping skills (recognize and prepare for early signs of relapse)	MA, SR: (Grant et al., 2017)
Mindfulness-based Elder Care	MBEC	(Mc Bee, 2009)	1hr ongoing	Group (nursing homes)	Frail elderly people and their caregivers	Diaphragmatic breathing, meditation, gentle yoga, and informal mindfulness practice	MBSR adapted to suit older adults with cognitive and physical disabilities.	Clinical case evidence in McBee (2009)
Mindfulness-integrated Cognitive Behavioural Therapy	MiCBT	(Cayoun, 2011)	1–1.5hr/week 8-12 weeks	Group	Transdiagnostic	Body scan, mindful breathing,	Exposure procedures, interpersonal skills training, and exercises for cultivating empathy, compassion, ethical behaviour	(Yazdanimehr, Omidi, Sadat, & Akbari, 2016)
Mindfulness-based Relationship Enhancement	MBRE	(Carson, Carson, Gil, & Baucom, 2004)	1.5–2.5hr/week 8 week + Full day retreat	Group (6-8 couples)	Teaching interpersonal practices for couple	MBSR adapted for couples. Body scan meditation, yoga exercises, and sitting meditation, informal mindfulness during routine activities training	Loving-kindness meditations focused on partner. Partner yoga. Mindful touching. Eye-gazing exercises. Application of mindfulness to both emotion-focused and problem-focused approaches to relationship difficulties.	(Carson et al., 2004)
Mindfulness-based Eating Awareness Training	MB-EAT	(J. L. Kristeller, Baer, & Quillian-Wolever, 2006)	1.5hr/week 9 weekly sessions with 3 monthly booster sessions	Group	binge-eating disorder	Mindful eating and awareness exercises focused on physical hunger and satiety cues, overall food intake, and physical, cognitive, social–environmental, and emotional triggers of bingeing. General (breath/open awareness) mindfulness	Educational material on eating-related self-regulatory processes including emotional vs. physical hunger triggers, gastric and sensory-specific satiety (SSS), food choice, and emotional regulation pertinent to self-concept and stress management.	(Kristeller & Wolever, 2010; Kristeller, Wolever, & Sheets, 2014)

Program	Common acronym	Reference	Length	Typical Format	Target	Mindfulness Components included	Distinguishing Characteristics	Selected Supporting Evidence
						meditation, guided eating meditations, and "mini-meditations"		
Mindfulness-based Art Therapy	MBAT	(Monti et al., 2006)	8 week	Group	Cancer patients	MBSR	Gender segregated art therapy for cancer patients integrated with MBSR. Art-based tasks that allow for focused expression of unpleasant emotions	(Jalambadani & Borji, 2019; Jang, Kang, Lee, & Lee, 2016; Monti et al., 2006)
Mindfulness based Childbirth and Parenting	MBCP	(Bardacke, 2012; Bardacke & Duncan, 2014)	9 weeks	Group	Pregnant people	Sitting meditation, body scan, mindful yoga, and loving kindness meditation. 1 day silent meditation	MBSR tailored and enhanced to address the concerns of pregnancy and early parenting. Training in mind-body pain coping practices, breastfeeding, postpartum adjustment and the social, emotional, and biological needs of the newborn. Formal and informal mindfulness practices postpartum (e.g., using walking meditation to comfort a crying baby).	(Duncan & Bardacke, 2010) Review citing supporting small trials (n<34)
Mindfulness-based Strengths Practice	MBSP	(Niemiec, 2014)	8 week	Group		Body scan, Mindful eating, Sitting meditation	Character strengths training (psychological processes or mechanisms that define core universal human virtues, for example one core virtue is wisdom and a character strength of that is curiosity; see Peterson & Seligman , 2004 for review of this literature).	(Ivtzan, Niemiec, & Briscoe, 2016)
Mindfulness-based Symptom Management	MBSM	(Monteiro & Musten, 2013)	8 week	Group	People with mood, stress, and pain-related conditions	Body scan, Mindful eating, Sitting meditation	Adaption of *Buddhist* ethics. E.g., Buddhist: 'refrain from killing' MBSM: respect mortality	None (reference is a guide)
Mindfulness-based Mind Fit Training	MMFT	(Jha, Stanley, Kiyonaga, Wong, & Gelfand, 2010)	Original: 24-hour, 8-week Brief: 8 hours	Group	Reduce attentional lapses in Military	4 hours mindfulness training, 4 hours discussion	Used to enhance military training	(Jha et al., 2015)

Program	Common acronym	Reference	Length	Typical Format	Target	Mindfulness Components included	Distinguishing Characteristics	Selected Supporting Evidence
Meditation Awareness Training	MAT	(Shonin, Van Gordon, Dunn, Singh, & Griffiths, 2014)	8 week	Individual or Group	Originally workplaces. Extended to others	Guided meditation and mindfulness exercises	Incorporates Buddhist concepts in a 'secular but traditional' way.	(Shonin, Van Gordon, Dunn, Singh, & Griffiths, 2014; Van Gordon, Shonin, & Griffiths, 2016)

MA: Meta-analysis; SR: Systematic Review

1.3. Research evidence for mindfulness and mental health

…over the years there has been a ratcheting upward of sophistication as the number of studies of meditation has exploded to more than one thousand per year. This tsunami of meditation research created a foggy picture, with a confusing welter of results. Beyond our focus on the strongest findings, we try to highlight the meaningful patterns within the chaos.

Goleman and Davidson (2017, pp. 22)

Mindfulness meditation became a popular topic of research following its applications in clinical psychotherapy from the 1970s onwards. Early research featured clinical case studies and quasi-experimental pre-post-tests (e.g., Goleman & Schwartz, 1976), but research has since broadened to include randomised controlled trials (RCTs), qualitative research, systematic reviews, and more recently meta-analyses. Mindfulness-based interventions have been shown to impact a broad range of mental health outcomes in RCTs including psychological distress, depressive symptoms, anxiety, and well-being (Goyal et al., 2014; Halladay et al., 2019; Khoury et al., 2013). But they have also received heavy criticism for small samples sizes and inappropriate comparison groups (Van Dam et al., 2017).

A narrative review of randomised controlled trials is commonplace in a thesis, but when there are hundreds of studies on a given research question it is challenging to provide an accurate and critical evaluation of the accumulated evidence (Gurevitch, Koricheva, Nakagawa, & Stewart, 2018). By contrast, meta-analyses are generally considered the top tier of evidence when developing health guidelines (Harbour & Miller, 2001). They are also better placed to resolve contradictory findings, identify sources of variation in the findings, and highlight the shortcomings to methodological rigour, than individual RCTs. They are, therefore, a powerful and robust way to provide a transparent and objective synthesis of the state of the current literature about mindfulness meditation.

There are two common, but dissimilar approaches to meta-analysis that reflect the goals of the research question (Gurevitch et al., 2018). In the first approach, the goal is to assess evidence for a specific intervention on a specific outcome in a specific population. This approach draws on a small, well-defined body of research and is useful for estimating the effect of the intervention in a specific population but cannot be easily generalised beyond that population. I will refer to this as the targetted approach. In the second approach, the goal is to make broader generalisations about the state of the literature. This approach draws on a broad and heterogeneous body of research (i.e., incorporating different populations, methodologies, or outcomes) and is useful for identifying fundamental problems and sources of heterogeneity. I will refer to this as the broad approach. For these reasons, in this section I will rely on the broader meta-analytic evidence linking mindfulness meditation to mental health with a particular focus on the populations of interest, modalities of interest, mechanisms of action, and intervention design, adherence, and fidelity. I will support these broader reviews with a selection of key empirical studies that warrant attention.

Important caveats

Meta-analyses are a strong source of evidence, but there are several factors to consider when interpreting them. First, not all meta-analyses are created equally. Like mindfulness research, the publication rate of meta-analyses has drastically increased over the last few decades (an increase of 2635% since 1990 compared to an overall increase of 132% in all research from 1990–2014; Ioannidis, 2016). Although meta-analyses are the most frequently cited publication-type (Patsopoulos, Analatos, & Ioannidis, 2005), their popularity and citation impact does not preclude them from criticism. To borrow from the title of Ioannidis' (2016) article, many meta-analyses are "redundant, misleading, and conflicted". Guidelines such as PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis; an adaptation of the 1999 QUOROM guidelines, Liberati et al., 2009) have been developed to improve the accuracy, clarity, and transparency of reporting meta-analyses. Although most authors of meta-analyses after 2009 report adhering to the PRISMA guidelines, few actually

do (e.g., the majority of systematic reviews adhered to only one-third of PRISMA items; Page & Moher, 2017). Quality is not guaranteed with adherence to PRISMA, but it does make weaknesses and limitations transparent. For these reasons, all meta-analyses in this thesis adhere to at least two-thirds of the PRISMA guidelines. While reviewing the eligible meta-analyses it became clear that few meta-analyses adhere to PRISMA item 5 ("*Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number").* The publication of protocols, pre-registration of research intent, and registered reports reduces the risk of publication bias and questionable research practices (in meta-analyses this would primarily include selective inclusion of studies and outcomes; see Quintana, 2018, for examples). I have prioritised the inclusion of meta-analyses that pre-registered their analysis plan (for instance on PROSPERO; https://www.crd.york.ac.uk/PROSPERO) or published a protocol, as well as those that use appropriate statistical procedures (e.g., to calculate effect sizes, conduct heterogeneity tests, examine publication biases, and appropriately deal with effect size dependence). Where possible, I also present relevant sensitivity, subgroup, and meta-regression analyses[12] to demonstrate the robustness of the meta-analytical results and discuss the likelihood of publication bias (i.e., the likelihood that small or non-significant effects have not been published).

Second, in meta-analyses that include studies with two or more treatment arms, or two or more treatment populations, the authors will often include multiple comparisons from the same study (i.e., control vs. treatment 1 and control vs. treatment 2, or, control vs. depressed diagnosed population and control vs anxiety diagnosed population). Doing so means that the effects are not independent of each other and dependent means have implications for the

[12] *Sensitivity analyses* examine how the meta-analyses findings are affected by changes in review-level methods (e.g., study inclusion criteria) or the data used from individual studies (e.g., risk of bias). *Subgroup analyses* address whether the meta-analyses findings vary by the characteristics of the included studies (e.g., brief interventions vs. long interventions; MBSR vs MBCT; clinical vs non-clinical participants). *Meta-regression* is an extension of subgroup analyses that includes quantitatively examining the effect of study characteristics on the summary effect sizes and the impact of those characteristics on heterogeneity (Liberati et al., 2009).

heterogeneity effects (in terms of an artificial reduction in heterogeneity) and may impact the pooled effect sizes.

Third, given the high publication rate of meta-analyses, it is important to consider the overlap from one meta-analysis to the next. While redundancy in meta-analyses is disconcerting, the sheer abundance of meta-analyses on the same or similar topics means the overlap is unavoidable. For instance, when reviewing previous meta-analyses of MBIs for children and adolescents, Dunning et al. (2018) identified a 60–90% overlap across four reviewed meta-analyses. Although the overall messages generally converged (mindfulness is "useful"), each group of authors had to make numerous decisions about how to combine, categorise, and interpret outcomes across multiple studies. The number of decisions made is not inherently a problem when considering a meta-analysis in isolation, but it can present challenges when trying to identify patterns across meta-analyses as the overall message is open to interpretation and the conclusions drawn from the meta-analyses are subject to 'double counting' (i.e., the results of overlapping studies are counted as evidence in multiple meta-analyses). Where I have used multiple meta-analyses to provide clarity on a single research question I will explicitly highlight the overlap.

Finally, it is important to remember that effect sizes in individual studies reflect the choice of the comparison group. That is, interventions themselves do not have effect sizes (Coyne, 2016); rather, the comparisons between the intervention and another 'group' demonstrate the magnitude of effect (an effect size) of the intervention relative to the comparison group.

Within-subjects effect sizes (e.g., the intervention at baseline vs. the intervention at follow-up) demonstrate change over time. In meta-analyses these effects are often operationalised as standardised mean *change* (SMC), however the change in outcomes is less attributable to the provision of the intervention because recovery can occur naturally (e.g., natural history effect). By contrast, between-subjects effect sizes (e.g., intervention vs control) demonstrate the effect or change over time relative to a comparator. In meta-analyses these

effects are often operationalised as standardised mean *differences* (SMD) and can be more readily attributed to the provision of the intervention. The specificity of the attributions will depend on the choice of control group.

Selection of an appropriate control group is driven by the study question; but what constitutes an appropriate control group has been widely debated (e.g., see: Borkovec & Sibrava, 2005; Mohr et al., 2009) and has been the subject of criticism in mindfulness-based research (Davidson & Kaszniak, 2015). Waitlist and treatment-as-usual (TAU) controls provide "a valuable initial evaluation of whether interventions have an impact on outcomes above and beyond standard care [TAU] or no treatment [Waitlist]" (Creswell, 2017, p.496). But waitlist control designs may inflate intervention effect sizes above no-treatment controls. Using an example from a network meta-analysis on CBT interventions for depression (a well-established treatment option), waitlist control designs were associated with exaggerated intervention effectiveness higher than that found in no-treatment controls (Furukawa et al., 2014). By comparison, an active control is the strongest test of an intervention and generally considered best practice because it is possible to demonstrate superiority (better than an established intervention), equivalency (clinical outcomes are not too different from an established intervention), or non-inferiority (not much worse than an established intervention). Demonstration of superiority, equivalency, or non-inferiority are dependent on the aim, design, and statistical plan of the trial (Lesaffre, 2008).

To distinguish effect size comparisons, the differing calculations for error variance in between-subjects and within-subject effects mean it is not advisable to lump the effects together (Schäfer & Schwarz, 2019). In psychological research, between-subjects effect sizes are typically smaller than within-subjects effect sizes; studies that are not pre-registered typically have larger effects sizes than studies that are pre-registered; and effect sizes are generally smaller when samples are larger (Schäfer & Schwarz, 2019). Finally, in a between-subject design, effect sizes are typically smaller when the comparison condition is more

robust. In turn, interpretation of effect sizes should reflect the quality of the control or comparison group.

With these points in mind, to aid interpretation I have provided the type of effect size, the comparison group and, where possible (for between-subjects effects) in order to give a more intuitive interpretation of the effect, I have also post-hoc calculated and presented the approximate number-needed-to-treat[13] (NNT; which I have rounded to the nearest whole person).

Search Method

To identify suitable meta-analyses and individual studies I used an informal PICOS approach (participants/populations, interventions, comparators, outcomes, and study design; described in Liberati et al., 2009) to define the relevant topics of interest for this review. PICOS topics include:

> **P** – populations of interest: Clinical and non-clinical adults; university students.
>
> **I** – interventions of interest: Mindfulness-based interventions, particularly online, mobile, and brief interventions.
>
> **C** – comparators of interest: Active controls as defined by Goyal et al., (2014; e.g., active non-specific controls are not a known therapy but match time and attention to the intervention group, e.g., attention control, educational control. Active specific controls that are a known therapy such as progressive muscle relaxation). I will cautiously include other control comparators (e.g., waitlist, no treatment, or treatment-as-usual).
>
> **O** – outcomes of interest: mental health (distress, depression, anxiety, stress), well-being, resilience, and college adjustment indicators.
>
> **S** – study designs of interest: Primarily: meta-analyses; selectively: randomised controlled trials, pragmatic trials.

I informally identified research relevant to the PICOS topics through a number of methods including research database searches, Google scholar alerts, searching trial registration

[13] Calls are being made by researchers (e.g., Lakens, 2013) to aid the interpretation of complex statistics by including more intuitively understandable statistics such as the common language effect size or the number-needed-to-treat (NNT). NNT is simply the number of participants that need to receive the intervention in order for one positive outcome to be observed (using Furukawa & Leucht's (2011) method). I used the Cohen's *d* and NNT calculator provided by (Magnusson, 2014).

websites (e.g., ANZCTR.org.au and clinicaltrials.gov), preprints (e.g., PsyArxiv), and forward and backtracking of citations. In the following sections I review this literature representatively, but selectively (and certainly not exhaustively). Finally, to aid readability and avoid "statisticalese", I have only provided necessary effect sizes in text and put supporting information in a summary table of important meta-analyses and key empirical studies, see Table 1.2.

1.3.1. Are mindfulness-based interventions effective in improving mental health in both non-clinical and clinical populations?

Clinical populations

The majority of research on mindfulness-based interventions has focused on psychologically distressed clinical populations. This is perhaps unsurprising, as the foremost manualised MBIs (e.g., MBSR and MBCT) were founded in clinical settings with the goal of treating clinical patients.

The strongest source of meta-analytic evidence for the efficacy and effectiveness of mindfulness-based interventions in clinical populations was commissioned by the USA Agency for Healthcare Research and Quality (Goyal et al., 2014a). In this meta-analysis, the strict inclusion of RCTs with active controls was intended to give clinicians greater confidence that the reported benefits were not simply the result of non-specific effects (e.g., attention and expectation effects). Only 3% of the examined published trials met the inclusion criteria. To add strength to their conclusions, Goyal et al. assessed the strength of the available evidence across four domains: risk of bias, directness of measures, consistency of finding, and precision of estimates. Overall, 47 RCTs were included and the meta-analytic results were presented in both a short peer-reviewed online article and a longer online report. Concerningly, less than 20% of the 47 trials included in this meta-analysis that used clinical samples measured harms or adverse effects in their reports; although where these data were measured, no harms were related to the intervention.

Goyal et al. (2014) found moderate-strength evidence that mindfulness programmes were associated with small improvements in anxiety and depression, and low-strength evidence for improvements in stress when compared with non-specific active controls (e.g., attention controls). More specifically, they reported relative improvements, ranging from zero to 44% improvement in anxiety, -5% deterioration to 52% improvement in depression, and 1% to 21% improvement in stress in the mindfulness group compared to the non-specific active control group. These rates corresponded to effect sizes of .38 [95% CI .12, .64] for anxiety at 8 weeks and .22 [95% CI .02, .43] for anxiety at 3–6 months; .30 [95% CI .00, .59] for depression at 8 weeks and .23 [95% CI .05, .42] at 3–6 months. No specific effect sizes were provided for stress because the strength of the evidence was deemed too low and the authors reported concerns of publication biases. Despite the modest effects reported here, the authors concluded that the small effects on anxiety and depression found between 2–6 months were 'comparable with what would be expected from the use of an antidepressant in a primary care population but without the associated toxicities' (Goyal et al., 2014a, p. 364). More specific effect size data were provided in the longer commissioned report available online (Goyal et al., 2014b); these are provided in Table 1.2.

Few studies in this meta-analysis used an active specific control (e.g., comparing mindfulness interventions to an existing acceptable treatment), and overall this evidence was deemed insufficient by Goyal et al. (2014). Even so, Goyal et al. (2014) reported that there was no evidence of equivalence or noninferiority when compared to an existing treatment such as progressive muscle relaxation or CBT across 20 RCTs, although these analyses were underpowered.

Following this line of reasoning, a recent meta-analysis compared MBIs to controls or to CBT on anxiety, stress, and depression outcomes in patients with anxiety and stress-related disorders (de Abreu Costa, D'Alò de Oliveira, Tatton-Ramos, Manfro, & Salum, 2019). Five of the 10 studies in this meta-analysis had already been included in Goyal et al. (2014). As reported in Table 1.2., de Abreu Costa and colleagues found that MBIs had small to moderate

effects on distress and internalising symptoms (a pooled outcome of measures of depressive and anxiety symptoms) relative to waiting list, exercise, or psychoeducation-related controls. But in a different analysis approach to Goyal et al. (2014), who analysed for equivalence or noninferiority, the team found no evidence for superiority of CBT over MBIs. In a final example, comparing MBIs with MBIs *plus* CBT, MBIs with added CBT were associated with moderate (but imprecise) effects on resilience that were similar to the effects of MBI alone, in a meta-analysis using both clinical and non-clinical samples for resilience (Joyce et al., 2018).

Hofmann, Sawyer, Witt, and Oh (2010) looked more closely at specific MBIs in a broad array of clinical patients, and provided some early evidence that the effects of MBI over time may differ by MBI programme. Although there was significant heterogeneity in the included 39 studies, the within-subjects effect sizes for MBCT were around g = .80 for both depression and anxiety, with precision estimates ranging from moderate to large; whereas the within-subjects effect sizes for MBSR were around g = .50 for both depression and anxiety with moderate precision estimates. Importantly, this meta-analysis demonstrated that MBCT was associated with reductions in depression symptoms in patients with *current* depression, despite originally being developed as a depression relapse prevention programme (Segal et al., 2013).

Building on Hofmann et al.'s work (2010) by looking more closely at MBCT, Kuyken et al. (2016) examined 1258 individual patients' data from nine randomised MBCT trials (one trial, Kuyken et al. 2008, was earlier included in Goyal et al., 2014). Five of the nine studies recorded adverse events, although these were only observed in three of the nine studies. There was low heterogeneity across the included trials. Here, the researchers found that at any particular time up to 60 weeks follow-up, approximately one-third as many patients in the MBCT group relapsed compared to the control group (when any control was included; HR = .69, 95%CI [.58, .82], p <.001). This Hazard Ratio reduced to about one-quarter (up to 60 weeks) when compared to active treatments (HR = .78) and to antidepressant medication (HR = .77), but still favoured MBCT. Importantly, the relapse rates held at around 26% reduced

hazard for MBCT patients up to 60 weeks, even when controlling for predictors of relapse, including baseline mindfulness, age of depression onset, and number of past episodes of depression (HR = .74, 95%CI [.61, .90], p =.003). MBCT was most effective for those with higher baseline depressive symptoms, lending support to the idea that MBCT offers more benefit to those with the greatest mental health needs. All of the authors on this study (excluding the statistician and an independent systematic reviewer) had some form of conflict of interest relating to financial gain associated with to mindfulness (books, courses etc) and the provision of MBCT to patients.

To lend additional credibility to Kuyken et al.'s review (given the extensive conflicts of interest), let us take a quick look at another project in which six of the studies included in Kuyken et al. (2016) made up 100% of the studies meta-analysed by an independent group, who reported no conflicts of interest. Here, Piet and Hougaard (2011) presented the Relative Risk (of relapse) in patients with recurrent MDD in remission. Piet and Hougaard found that MBCT reduced the risk of relapse by 34% compared to controls. Further, there was a 43% relative risk reduction for patients with three or more previous episodes. Finally, they found that MBCT may be as effective as (but not more effective than) maintenance antidepressant medication. The details of these effects are reported in Table 1.2. Thus, despite their potential conflicts of interest, the conclusions reached by Kuyken et al. (2016) appear to be supported by other, impartial reviews (e.g., Piet & Hougaard, 2011).

The clinical value of MBCT has been demonstrated in the growing cumulative evidence of its effectiveness, and as a result MBCT is beginning to bridge the research-to-practice gap and is increasingly being offered in community and public healthcare settings, with some success. For example, patient data were acquired from five mental health services in the United Kingdom that use MBCT in regular practice (N = 1554 Tickell et al., 2019). Data from the Patient Health Questionnaire (PHQ-9; scores range from 0–27), a screening tool used to diagnose major depression and grade symptom severity (Kroenke, Spitzer, & Williams, 2001), were collected as part of routine practice. Using commonly accepted cut-off scores,

approximately half of the patients were currently depressed at baseline (n = 828 with PHQ-9 ≥ 10, 53%), while the other half were not (n = 726 with PHQ-9 < 10, 47%). MBCT was associated with improvement in PHQ-9 scores in both the depressed and not-depressed subgroups. Importantly, almost half of those who entered the programme as 'depressed' left it as 'not currently depressed' (45%), and almost all who entered the programme as 'not depressed' remained 'not currently depressed' (96%). A six or more-point increase or decrease of PHQ-9 scores from baseline to follow up was used to indicate a 'reliable deterioration' or 'reliable improvement', respectively. Here, 41% of patients depressed at baseline reliably improved and just over 2% reliably deteriorated. Further, over one-third of patients initially depressed at baseline had reliably recovered by follow up; that is, they moved from PHQ-9 ≥ 10 to PHQ-9 < 10, and their PHQ-9 scores dropped by six or more points. Approximately 8% of patients not depressed at baseline reliably improved and 4% reliably deteriorated. Note, however, the PHQ-9 cut-offs to be 'not depressed' are scores below 10, meaning there is a ceiling effect for opportunity to reliably improve. The rate of deterioration in both subgroups was reportedly comparable to other treatments. Standardised mean changes (Cohen's *d* within-subjects effect sizes), or change over time, was moderate overall, small but significant for not-depressed patients, and large for depressed patients; effect size details are presented in Table 1.2. Importantly, this study demonstrates the real-world validity and effectiveness of MBCT and adds to growing evidence that MBCT is beneficial for currently depressed patients, as opposed to only being useful to prevent relapse in recovered patients – the original aim of the programme.

A contemporary of Goyal et al.'s (2014) meta-analysis that comes to far more glowing conclusions is that of Khoury et al. (2013). Both Goyal et al. (2014) and Khoury et al. (2013) incorporated different MBIs; however, where Goyal et al. (2014) used more stringent criteria to select clinical studies with higher methodological rigour, Khoury et al. (2013) used a more typical broad-style meta-analytic approach. Khoury et al.'s (2013) meta-analysis is the largest

and broadest of those included in this thesis (k[14] = 209 mindfulness-based therapy studies; N = 12,145; studies published by 10 May 2013), including a wide array of mindfulness-based interventions for both clinical and *non*-clinical samples in addition to non-randomised pre-post studies as well as controlled trials.

One puzzling exclusion criterion for this meta-analysis was the decision to exclude trials that authors deemed to be part of another treatment, such as ACT and DBT trials, but not MBCT. By way of example, the authors excluded trials 'such as cognitive behaviour protocol, because it is difficult to differentiate the effect of mindfulness from other components' (Khoury et al., 2013, p. 764). It is interesting that they chose to exclude MBIs that incorporate cognitive-behavioural therapies, but not MBCT, a mindfulness-based intervention that relies heavily on cognitive therapy. That aside, the otherwise broad and diverse inclusion of studies in this meta-analysis was useful because it demonstrates that early research was dominated by nonrandomised, pre-post, lower quality studies which, in general, are associated with stronger effects.

Of the 209 studies included in this meta-analysis, 72 used pre-post designs (34.4%), 67 used waitlist-controlled or no-treatment-controlled designs (32.1%), and 68 used treatment-controlled designs (32.5%). The designs of two studies were not reported, and just over half of the included studies were randomised (52.2%, 109 studies). Khoury et al. (2013) assessed the quality of the included studies using a combination of Jadad et al.'s criteria (Jadad et al., 1996) and other items relating to mindfulness studies, such as the training of the therapists. Quality scores could range from 0–11 for controlled studies and 0–5 for pre-post studies, with higher scores indicating higher quality. In the absence of any author description of the range of quality scores across designs, I calculated the descriptive statistics for several of the following designs using data from the supplementary materials. Pre-post studies had an average quality rating of 2.93 out of 5 (SD = 1.19); waitlist-controlled or no-treatment-controlled studies had

[14] For convenience I will use k to represent the number of studies included in the meta-analyses to distinguish it for N/n (N = total participants, n = subgroup of participants).

an average quality rating of 4.84 out of 11 (SD = 2.19); and treatment-controlled studies had an average quality rating of 7.25 out of 11 (SD = 4.91).

As presented in Table 1.2, in pre-post and wait-listed trials, mindfulness-based therapies were associated with statistically significant moderate to large effects on mindfulness, anxiety, and depression. In treatment-controlled trials, mindfulness-based therapies were associated with moderate effects on mindfulness. Despite most of the treatment-controlled studies including either anxiety or depression as study outcome measure, no effect sizes were reported for treatment-controlled studies on these outcomes and no justification was provided for this decision.

Across the broad outcomes, mindfulness-based therapies were more effective than a range of alternative interventions including psychoeducation, supportive therapy, and relaxation (*g*'s ranging from .19 to .61, favouring mindfulness). Unsurprisingly, there was high heterogeneity between these interventions. The effects of mindfulness-based interventions were not statistically or significantly different from CBT or behavioural therapies (k = 9, g = -.07, 95%CI [-.26, .16], p = .60), nor from pharmacological treatments (k = 2, g = .13, 95%CI [-.11, .37], p = .27), although I suspect these tests were underpowered. Khoury et al. (2013) reported statistically significant moderate effects (with moderate precision) in both pre-post and waitlist-controlled studies using non-clinical samples collectively across the broad outcomes (*g*'s .65 and .62 for pre-post and waitlist-controlled, respectively). Finally, and perhaps most importantly, the reported cumulative effect sizes were negatively moderated by year of publication and study quality. Put plainly, lower quality and earlier research appears to drive the moderate to large effect sizes reported in this meta-analysis.

Non-clinical populations

Other more recent meta-analyses have focused exclusively on the effects on mindfulness in non-clinical or healthy populations. For instance, in a meta-analysis on MBIs in working adults, MBIs were associated with moderate effects on psychological distress (*g*'s

= .68; with moderate to large precision estimates) both over time (within-group, pre-post effects) and in comparison with inactive controls.

Other meta-analyses on healthy populations have included broader meditation interventions. The largest was conducted by Sedlmeier et al. (2012), who conscientiously published an update in 2018 (Sedlmeier, Loße, & Quasten, 2018). In their first meta-analysis, these researchers identified 163 mindfulness, transcendental, or 'other' meditation studies that were published between 1970 and September 2011 as peer-reviewed journal articles (n = 125), book chapters (n = 28) or research dissertations (n = 10). Of these controlled studies, 46 were categorised as mindfulness meditation (n = 2131; 11 were previously included in Khoury et al., 2013). Using correlational effect sizes ($\bar{r}$) to present the difference between meditation and control groups (correlation between group membership and dependent variables), mindfulness meditation was specifically associated with strong effects ranging from $\bar{r}$ = .32 to .35 for stress, mindfulness (with evidence of heterogeneity as indicated by large population variance statistic), and state anxiety, with more moderate effects of $\bar{r}$ = .25 and .29 for well-being and trait anxiety, respectively. The details of these effects are presented in Table 1.2.

In recognition of the fact that many of these studies were mindfulness specific, two of the authors reanalysed mindfulness-specific studies in a separate publication (Eberth & Sedlmeier, 2012). In this meta-analysis they re-categorised mindfulness studies as MBSR or MBI, and demonstrated that although they were drawing on small studies, MBSR had higher correlative effects on anxiety than more broadly defined MBI (r =.37 for MBSR vs r = .12 for MBI). Other effects on anxiety and well-being ranged between r = .26 and .37.

In the meta-analytic update, Sedlmeier, Loße, and Quasten (2018) identified a further 65 meditation studies conducted in healthy populations between 2011 and 2015. Of these new studies, 18 were specifically categorised as an MBI or MBSR (n = 1504; one was previously included in Khoury et al., 2013), although the authors stated that the other meditation techniques are usually categorised as mindfulness elsewhere. Keeping with their original categorisations, the overall effect of MBIs and MBSR was $\bar{r}$ = .24 and .22, both with evidence

of heterogeneity. As in previous research, the effect sizes were considerably smaller when MBSR was compared with active control groups $\bar{r}$ = .12 (no evidence of heterogeneity; fewer than three MBIs compared with active controls, so this analysis was deemed inappropriate for the MBI subgroup). The details of these effects are presented in Table 1.2. Although the distinction between 'conventional' control groups and active control groups was a key component in the analyses, at no stage did the authors define conventional control groups. Given their comparison with active controls, however, I assume conventional controls were waitlisted or no-treatment control groups.

In conclusion, although mindfulness meditation has been applied to many mental health outcomes, the body of work relating to depression, relapse prevention, and anxiety in clinical samples is by far the most robust. MBIs appear to have more of an impact in clinical populations. But when considering the differences in effect between clinical and non-clinical populations, it is important to recognise the possibility of a floor effect for non-clinical populations. Put another way, clinical populations have more room to improve their mental health. It is also perhaps unsurprising that MBCT has stronger and more precise effects on depression and anxiety in clinical samples, given that it was developed as a depression relapse prevention programme (Segal et al., 2013). By contrast, MBSR was developed to help people with chronic health problems deal with the psychological and emotional stress associated with their condition, and has since been more globally applied (Kabat-Zinn, 2011).

Across hundreds of individual studies in both clinical and non-clinical adults, mindfulness-based interventions have been associated with improvements in mental health. The current findings, while modest, indicate that MBIs have a small-to-moderate effect on mental health outcomes compared to active controls. Although these effects are smaller than when they are compared to waitlist controls, the comparison to an active condition provides the strongest evidence that MBIs have a causal association with improved mental health. The direction of the effect (i.e., that MBIs improve mental health) converged across all of the meta-analyses reviewed here.

Many of the earlier studies reviewed here have been plagued by poor-quality evidence, inappropriate control groups (a heavy reliance on pre-post and no-treatment controls), and other methodological features that indicate high risk of bias. The meta-analysis by Goyal et al. (2014) is easily the most robust evidence available thus far, and demonstrates that in clinical populations MBIs have some favourable impacts.

But even Goyal et al.'s (2014) analysis is not without its critics. Some researchers have responded with criticism for the lack of inclusion of studies that use usual care or 'treatment-as-usual' (TAU) as a comparison, when the sample is clinically distressed (Loucks, 2014; Walach, Schmidt, & Esch, 2014). For example, Loucks pointed out that excluding TAU contradicts the USA's Institute of Medicine's (2009) national recommendations: that MBI should be compared to usual care for the treatment of anxiety, depression, pain, cardiovascular risk factors, and chronic diseases. It should be noted, however, that although TAU accounts for the passage of time, it does not account for demand characteristics and placebo effects (Baer, 2003). Another problem with TAU as a comparison is that it varies so greatly across settings that it is hard to generalise. But when considering the ethical dilemmas associated with clinical equipoise (where one treatment is thought to far outperform another), in the absence of other acceptable active specific comparisons, TAU should be considered more robust than a non-specific active control that controls only for dose and time spent. In the face of intractable mental ill-health (e.g., depression remission), it is undoubtedly unethical to expect patients to consent to receive an attention control when usual care is available.

Table 1.2.

Summary of meta-analytic and important individual study effects of MBI on selected mental health outcomes in clinical and non-clinical populations

Study	Population	MBI	k	Effect size	Distress	Anxiety	Depression/ depressive symptoms	Stress	Resilience	Well-being	Mindfulness	Extra
(Eberth & Sedlmeier, 2012)	**Non-clinical**	**MBI; MBSR**	**38**	***r***	-	**Pooled**: r = .28; *k* = 9; *n* = 454 **MBSR**: *r* = .30; *k* = 5; *n* = 245 **MBI**: *r* = .26; *k* = 4; *n* = 209	-	**Pooled**: *r* = .37; *k* = 6; *n* = 331 **MBSR**: *r* = .37; *k* = 6; *n* = 331	-	**Pooled**: *r* = .31; *k* = 13; *n* = 604 **MBSR**: *r* = .37; *k* = 10; *n* = 450 **MBI**: *r* = .12; *k* = 3; *n* = 154	-	
(de Abreu Costa, D'Alò de Oliveira, Tatton-Ramos, Manfro, & Salum, 2019)	**Clinical:** patients with anxiety and stress-related disorders	**MBSR; MBCT**	**10**	**DSMC** [a]	**vs. control:** -.45; 95%CI [-.70, -.21]; *p* = .0003; *k* = 5; *n* = 288 **vs. CBT:** .002, 95%CI [-.47, .47]; *p* = .9933; *k* = 3; *n* = 203	**vs. control** -.38; 95%CI [-.64, -.12]; *p* = .0038; *k* = 6; *n* =460 **vs. CBT:** .17; 95%CI [-.06, -.39], *p* = .142, *k* = 4; *n* = 275	**vs. control** -.38; 95%CI [-.64, -.12]; *p* = .0038; *k* = 6; *n* =460 **vs. CBT:** .17; 95%CI [-.06, -.39], *p* = .142, *k* = 4; *n* = 275	-	-	-	-	CBT was not superior to MBI
(Goyal et al., 2014a)	**Clinical**	**MBI; MBSR; MBCT; other meditation programs (not included here)**	**47**	**Relative difference**[b] **SMD (from full-report**[c]**)**	-	**vs. non-specific active** 0 to 44% moderate strength of evidence for improvement; *k* = 8, *n* = 647. **vs. non-specific active at 12w**[c]**:** SMD: -.40; 95%CI [-.71, -.08]; *p* = .039; *k* = 6 **vs. active at 12w**[c]**:** SMD: .06; 95%CI [-.20- .32]; *p* = .074; *k* = 8	**vs. non-specific active** -5 to 52% moderate strength of evidence for improvement; *k* = 10, *n* = 806. **vs. non-specific active at 12w**[c]**:** SMD: -.32; 95%CI [-.66, .01]; *p* = .012; *k* = 7 **vs. active at 12w**[c]**:** SMD: -.16; 95%CI [-.36- .03]; *p* = .138; *k* = 9	**vs. non-specific active** -1 to 44% low strength of evidence for improvement; *k* = 9, *n* = 735. **vs. non-specific active at 4m**[c]**:** SMD: -.20; 95%CI [-.50, .10]; *p* = .546; *k* = 6 **vs. active at 4m**[c]**:** SMD: -.03; 95%CI [-.23- .17]; *p* = .321; *k* = 6	-	-	-	

Study	Population	MBI	k	Effect size	Distress	Anxiety	Depression/ depressive symptoms	Stress	Resilience	Well-being	Mindfulness	Extra
(Halladay et al., 2019)	**Non-clinical:** university students	**MBI**	**41**	**SMD**	-	**vs. passive control:** SMD: -.53, 95%CI [-.78, -.29], p < .0001, n = 1185, k = 20 **vs. active control:** SMD: .13, 95%CI [-.08, .34], p = .14, n = 663, k = 7	**vs. passive control:** SMD: -.49, 95%CI [-.68, -.30], p < .00001, n = 1266, k = 20 **vs. active control:** SMD: .04, 95%CI [-.13, .22], p = .18, n = 830, k = 9	**vs. passive control:** SMD: -.39, 95%CI [-.50, -.27], p < .00001, n = 1643, k = 23 **vs. active control:** SMD: -.08, 95%CI [-.32, .16], p = .09, n = 605, k = 6	-	-	-	**vs. passive equivalent BDI:** -4.1, 95%CI [-5.7, -2.5] **vs. passive equivalent BAI:** -3.8, 95%CI [-5.6, -2.1] **vs. passive equivalent PSS**: -2.4, 95%CI [-3.1, -1.7]
(Hofmann et al., 2010)	**Clinical**	**MBSR; MBCT**	**39**	**Hedge's *g***	-	**Pooled:** **Pre:post:** g = .63; 95%CI [.53, .73]; p <.01; N = 1140 **MBCT** **Pre:post:** g = .79; 95%CI [.45, 1.13]; p <.001; k = 6 **MBSR** **Pre:post:** g = .55; 95%CI [.44, .66]; p <.001; k = 20	**Pooled:** **Pre:post:** g = .59; 95%CI [.51, .66]; p <.01; N = 1140 **MBCT** **Pre:post:** g = .85; 95%CI [.71, 1.00]; p <.01; k = 9 **MBSR** **Pre:post:** g = .49; 95%CI [.42, .56]; p <.01; k = 19	-	-	-	-	-	
(Joyce et al., 2018)	**Clinical; non-clinical**	**MBI; MBI+CBT**	**11**	**SMD**	-	-	-	-	**MBI+CBT:** d = .51, 95% CI [.12, .91]; k = 5; n = 407 **MBI:** d = .46, 95% CI [.10, .82]; k = 2; n = 124 **MBI at 6m:** d = .58, 95% CI [.27, .89]; k = 3	-	-	

Study	Population	MBI	k	Effect size	Distress	Anxiety	Depression/ depressive symptoms	Stress	Resilience	Well-being	Mindfulness	Extra
(Khoury et al., 2013)	**Clinical; non-clinical**	**MBSR; MBCT**	**209**	**Hedge's *g***	-	**Pre:post:** *g* = .89; 95%CI [.71, 1.08], *p* < .001; *k* = 10 **vs. WL:** *g* = .96; 95% CI [.67, 1.24]; *p* < .001; *k* = 4	**Pre:post:** *g* = .69; 95%CI [.52, .86]; *p* < .001; *k* = 5 **vs. WL:** *g* = .53; 95%CI [.32, .73]; *p* < .001; *k* = 8	-	-	-	**Pre:post:** *g* = .69; 95% CI [.59, .80]; *p* < .001; *k* = 42 **vs. WL:** *g* = .53; 95%CI [.42, .63]; *p* < .001; *k* = 28 **vs. TX:** *g* = .42; 95%CI [.27, .57]; *p* < .001; *k* = 23	
(Kuyken et al., 2016)	**Clinical:** patients with recurrent depression	**MBCT**	**6**	**Hazard Ratio** [d]	-	-	**vs. all controls within 60 weeks:** HR = .69, 95%CI [.58, .82], *p* <.001, *k* = 6, *N* = 1248 (554 relapses). **vs. active controls within 60 weeks:** HR = .78, 95%CI [.64, .96], *p* = .02, *k* = 5, *N* = 892 (385 relapses) **vs. m-ADM within 60 weeks:** HR = .77, 95%CI [.60, .98], *p* = .03, *N* = 637 (266 relapses).	-	-	-	-	
(Ma, Zhang, & Cui, 2019)	**Clinical; non-clinical:** university students	**MBI**	**25**	**SMD**	-	-	**Pooled:** SMD: .52, 95%CI [.39, .65], *n* = 2472, *k* = 26 **Universal:** SMD: .41, 95%CI [.28,	-	-	-	-	

Study	Population	MBI	k	Effect size	Distress	Anxiety	Depression/ depressive symptoms	Stress	Resilience	Well-being	Mindfulness	Extra
							.55], *k* = 10 **Selective:** SMD: .44, 95%CI [.18, .70], *k* = 6 **Indicated:** SMD: .88, 95%CI [.64, 1.11], *k* = 7					
(Piet & Hougaard, 2011)	**Clinical:** patients with recurrent MDD in remission	**MBCT**	**6**	**Relative Risk (of relapse)**	-	-	**vs. control:** RR = .66**;** 95%CI [.55, .82]; *p* = .0001; *n* = 408 **vs. m-ADM:** RR = .80; 95%CI [.60, 1.08]; *p* = .15; *n* = 56	-	-	-	-	MBCT reduced the risk of relapse by 34% compared to control 43% RR reduction for patients with 3+ previous episodes. MBCT may be as effective as maintenance antidepressant medication (m-ADM)
(Sedlmeier et al., 2012)	**Non-clinical**	**MBI**	**163**	***r***	-	**vs. control:** **Trait**: *r* = .29; *k* = 11; *n* = 610 **State:** *r* = .32; *k* = 6; *n* = 200	-	**vs. control:** *r*= .35; *k* = 10; *n* = 419	-	**vs. control:** *r*= .25; *k* = 17; *n* = 1067	**vs. control:** *r*= .34; *k* = 16; *n* = 1005	
(Sedlmeier et al., 2018)	**Non-clinical**	**Meditation (i.e., not just MBI)**	**65**	***r***	-	**vs. control:** **Trait**: *r* = .13; *k* = 6; *n* = 300 **State:** *r* = .08; *k* = 11; *n* = 596 **vs. active control:** *r* = .09; *k* = 3; *n* = 153	**vs. control:** *r*= .11; *k* = 9; *n* = 889	**vs. control:** *r* = .32; *k* = 15; *n* = 1375 **vs. active control:** *r* = .15; *k* = 6; *n* = 404	-	**vs. control:** *r* = .27; *k* = 12; *n* = 1111 **vs. active control:** *r* = .18; *k* = 3; *n* = 238	**vs. control:** *r* = .32; *k* = 33; *n* = 3666 **vs. active control:** *r* = .11; *k* = 6; *n* = 310	
(Spijkerman, Pots, &	**Clinical; non-**	**Online**	**15**	**Hedge's *g***	-	**Pooled:** *g* = .22, 95%CI	**Pooled:** *g* **=** .29, 95%CI	**Pooled:** *g* = .51, 95%CI	-	**Pooled**: *g* **=** .23, 95%CI	**Pooled:** *g* **=** .32, 95%CI	

Study	Population	MBI	k	Effect size	Distress	Anxiety	Depression/ depressive symptoms	Stress	Resilience	Well-being	Mindfulness	Extra
Bohlmeijer, 2016)	**clinical**	**MBI**				[.05, .39], *p* <.05, *k* = 11 **Clinical**: *g* = .41, 95%CI [.09, .72], *p* <.05, *k* = 3 **Non-Clinical**: *g* = .10, 95%CI [-.19, .39], n.s , *k* = 3	[.13, .46], *p* <.01, *k* = 12 **Clinical**: *g* = .41, 95%CI [.07, .76], *p* <.05, *k* = 3 **Non-Clinical**: *g* = .21, 95%CI [-.07, .50], n.s , *k* = 4	[.26, .75], *p*<.001 , *k* = 11 **Non-Clinical**: *g* = .47, 95%CI [.20, .73], *p*<.01 , *k* = 9		[.09, .38], *p* <.01, *k* = 9 **Clinical**: *g* = .43, 95%CI [.20, .66], *p* <.01, *k* = 3 **Non-Clinical**: *g* = .19, 95%CI [-.02, .41], n.s , *k* = 2	[.23, .42], *p* <.001, *k* = 12 **Clinical**: *g* = .56, 95%CI [.24, .87], *p* <.01, *k* = 1 **Non-Clinical**: *g* = .32, 95%CI [.21, .42], *p* <.001, **k** = 8	
(Tickell et al., 2019)	**Clinical:** five mental health services, UK	**MBCT**	-	**Pre:post Cohen's *d*** **SMC**	-	-	**Pooled:** *M* Δ = 2.94; *d* = .48, *p* <.001; *N*= 1554 **Not depressed:** *M* Δ = .98; *d* = .33; *p* <.001; *n* = 726 **Depressed:** *M* Δ = 4.66; *d* = .86; *p* <.001; *n* = 828	-	-	-	-	
(Virgili, 2015)	**Non-clinical:** working adults	**MBI**	**19**	**Hedges's *g***	**vs. inactive control** *g* = .68; 95%CI [0.48, 0.88]; *p* <.001; *k* = 10; *n* = 676 **pre:post** *g* = .68, 95%CI [0.58, 0.78]; *p* <.001; *k* = 19; *n* = 652	-	-	-	-	-	-	

a = Difference in standardised mean change . b = Relative difference is the change score of intervention minus the change score of the control/10, * 100 to provide a %. d = Hazard Ratio (i.e. the ratio of hazards) = Hazard in the intervention group ÷ Hazard in the control group.

1.3.2. Are mindfulness-based interventions effective at improving mental health in young adults and university students?

MBIs – both universal and targeted –may be well suited to university student populations given their wide range of benefits, minimal ongoing costs, and capacity to be practiced in a wide range of settings. Growing evidence supports the idea that both universal and targeted interventions are well-placed to meet the mental health needs of university students (e.g., Bamber & Kraenzle Schneider, 2016; Conley, Durlak, Shapiro, Kirsch, & Zahniser, 2016; Davies, Morriss, & Glazebrook, 2014; Farrer et al., 2013; Fernandez et al., 2016; Ryan, Shochet, & Stallman, 2010), but less is known about the specific types of interventions that may be suitable for students. Many researchers studying the effectiveness of MBI have used students as a convenience sample; as such their results are more easily generalizable to student populations. The emerging data base suggests that MBIs have positive impacts on student mental health, particularly when targeting specific individuals such as those undertaking courses that typically cause high stress or those who have existing mental health needs.

For instance, MBIs were associated with a host of small to moderate improvements in university students' mental health outcomes in a preregistered meta-analysis of 41 RCTs (Halladay et al., 2019). These improvements included significant reductions in depression, anxiety, and perceived stress (ranging from SMD: -.39 [stress] to -.53 [anxiety]) when compared to a passive control (e.g., no intervention or waitlist). A post-hoc numbers-needed-to-treat (NNT) analysis revealed that 6–8 students need to receive a MBI in order for one student to have a positive outcome and these effects did not hold when compared to more rigorous control groups (e.g., active controls).

Effects also differed depending on the type of MBI: MBCT-based interventions were associated with significantly stronger effects than MBSR-based interventions (Halladay et al., 2019). Halladay et al., (2019) also back-transformed the SMDs into scores on widely used mental health measures (e.g., Beck Depression Inventory [BDI], Beck Anxiety Inventory [BAI], and Perceived Stress Scale [PSS]). When the stronger MBCT interventions were

excluded, these back-transformations indicated that the small to moderate effect sizes were perhaps less clinically meaningful than anticipated. Here, back-transformations indicate an approximate -2.5 point change on BDI, BAI, and PSS; measures which range from 0-60 (BDI and BAI) and 0-40 (PSS). Despite significant heterogeneity in the longer studies (included in the depression and anxiety analyses), there were no statistically significant differences between the effects of brief (2–8 week) or longer (8+ week) interventions. However, the quality of the included studies was also low to very low with a high risk of bias, which primarily reflected the lack of intention-to-treat analyses as well as the lack of blinding of participants, personnel, and outcome assessment.

Another meta-analysis compared university-based MBI for depressive symptoms by target (i.e., universal vs. selective vs. indicated; K = 22, N = 2472; Ma, Zhang, & Cui, 2019). Here, *universal* interventions referred to those where all students were eligible; *selective* interventions referred to those that included specific student populations at greater risk of depression (e.g., first-year students and medical students); and *indicated* interventions were those that included only clinically distressed students. Ma et al. (2019) found significant reductions in depressive symptoms, with effect sizes (SMD) of .41 (universal, k = 10), .44 (selective, k = 6), and .88 (indicated, k = 6). An effect size of .4 means almost 8 students need to receive the universal or selective MBI for one to improve, whereas only 3.5 students needed to receive the indicated MBI for one to improve.

One meta-analysis in tertiary students (which included many of the MBI already in Halladay et al., 2019) found no difference between the effects of yoga, meditation, or mindfulness on mental health outcomes (Breedvelt et al., 2019). Consistent with previous research, these interventions were associated with moderate improvements in depression, stress, and anxiety (g's = .42 to .46). In another meta-analysis which targeted medical students, 19 MBI (N = 1815, including nonrandomised designs) were associated with significant improvements in depressive symptoms, anxiety, and stress, with SMD's ranging from -.44 to -.54 (McConville, McAleer, & Hahne, 2017; seven of the studies included here were also included in Halladay et al.'s [2019] meta-analysis of 41 studies).

The reviewed meta-analyses, while modest, provide further evidence that MBIs have positive impacts on student mental health, but that these effects may be smaller when delivered universally and when compared to active controls (i.e., existing interventions).

1.3.3. On the role of individual practice, dose, and brief interventions

One practical consideration for mindfulness-based interventions concerns dosage and setting; that is, how much mindfulness practice is required in order to reap the benefits, and whether benefits may be gained by practicing alone (Davidson & Dahl, 2018)? A traditional MBI (e.g., MBSR and MBCT) is an eight-week group-based programme with a set, manualised curriculum. In addition to regular 2–3-hour weekly group-based classes, MBSR and MBCT involve a half or full-day retreat and intensive individual practice requirements, often termed 'home practice'. For both MBSR and MBCT, formal individual practice consists of 45 minutes per day, six days per week; for MBSR (but not MBCT), informal individual practice consists of an additional 15 minutes per day, six days of the week. A commitment to individual practice is considered essential if therapeutic benefit is to be gained (Kabat-Zinn, 2013; Segal et al., 2013; Vettese, Toneatto, Stea, Nguyen, & Wang, 2009). This is not always feasible for meditators however (Carmody & Baer, 2009), and may be especially problematic for clinical populations, since psychological ill-health can compromise the capacity to adhere to treatment requirements (Prince et al., 2007). Despite the stated importance of individual practice, many researchers neither record nor report adherence to this essential component, and only recently has the relation between individual practice and outcomes been formally examined (Lloyd, White, Eames, & Crane, 2018; Parsons, Crane, Parsons, Fjorback, & Kuyken, 2017).

Individual practice

In a meta-analysis of MBSR and MBCT studies (k = 43; N = 1427), participants completed on average only 64% of their recommended individual practice, even when less rigorous studies were excluded (Parsons et al., 2017). Post-course practice rates are also notoriously low. In a review of five studies, post-course practice rates ranged from less than 15

minutes once a week to 20 minutes per day (Vettese et al., 2009). Given that post-MBSR practice rates predict lower levels of subsequent stress (McClintock, Brown, Coe, Zgierska, & Barrett, 2019), these low rates of adherence to the practice guidelines raise serious questions about the real-world effectiveness of MBI.

The low rates of individual practice in MBSR and MBCT participants may reflect low intervention fidelity. In a systematic review of 14 MBSR and MBCT studies (six of which were included in Parsons et al., 2017), only two of the 14 studies adhered to the MBSR and MBCT curriculum guidelines (Lloyd et al., 2018). Four of the eight MBSR studies did adhere to the formal practice recommendations, but only one included the informal guidelines as mandated in the MBSR curriculum protocols. Lloyd et al. (2018) reported a higher number of adherent MBCT studies than I report here (e.g., they included Crane et al., 2014; Perich, Manicavasagar, Mitchell, & Ball, 2013); however, it is worth noting that both Crane et al. (2014) and Perich et al. (2013) recommended 40 minutes of practice over a period of eight weeks or less, despite the fact that the MBCT curriculum mandates 45 minutes for eight weeks. Further, the first author of one of the studies wrongly attributed as having intervention fidelity (Crane et al., 2014) is also the last author on Lloyd et al. (2018). Even so, across the studies reviewed by Lloyd et al., (2018; excluding those already included in Parsons et al., 2017) despite the rate of individual practice participants were recommended to complete, individual practice rates ranged from 14.9% (Davidson et al., 2003) to 83.8% (Speca, Carlson, Goodey, & Angen, 2000), indicating that there is great variability in practice rates even when practice recommendations are reduced.

It is also important to note that adherence to individual practice guidelines is self-reported in many of the studies. When the experimenter is leading the mindfulness practice (and relatedly, when the experimenter has a strong commitment to their own personal mindfulness practice) there may be a higher risk of allegiance bias[15] (Meichenbaum &

[15] Allegiance effects are well-documented in psychotherapy research. Luborsky et al., ([1999] 2006) present convincing data to demonstrate that the treatment favored by the investigator tends to produce the superior outcome. They found that allegiance accounted for 69% of the outcome variance (k = 60, N = 5627). Westen, Novotny, and Thompson-Brenner (2004) converted Luborsky et al.'s (1999) multiple

Lilienfeld, 2018) which may result in reporting biases regarding adherence (Coronado-Montoya et al., 2016). If this is the case in the aforementioned studies, it is also plausible that the self-reported rates of adherence may be inflated due to some form of therapeutic alliance to the teacher/researcher, in addition to the regular concerns of social desirability bias. Unfortunately, it is not common practice for mindfulness-based researchers to disclose whether or not they are actively involved in personal mindfulness practice, and many publications do not report who delivered the intervention (Van Dam et al., 2018; Davidson & Dahl., 2018). Thus, it is impossible to go beyond conjecture at this point, except to suggest that participants are unwilling or unable to adhere to such hefty individual practice commitments, and that future researchers should improve trial reporting (in particular their reporting of adherence and conflicts of interest).

Dose response

What about the relation between individual practice and clinical outcomes (i.e. a 'dose–response relationship')? Returning to Parsons et al., in the 28 (of 43) studies where dose response data were available, individual practice and intervention outcomes were significantly related overall (r= .26, 95%CI [1.19, .34], p <.0001); they did not differ greatly between clinical (k = 22, r = .25) and non-clinical populations (k = 5, r = .29), or by design (RCT k = 15, r = .26 vs non-randomised k = 4, r = .19, p =.01). Importantly, this finding also held true in studies where psychological health was an outcome (k = 19, r = .30, 95%CI [.21, .38], p <.0001).

Lloyd et al. (2018) reported mixed but generally positive results for the relation between individual practice and outcomes. Drawing on individual studies, in Davidson et al. (2003) there was no relation between individual practice and outcome – although this is unsurprising given that only 15% of participants met the recommended practice guidelines. In another study, by Bondolfi et al. (2010), the rate of individual practice did not significantly differ between those who relapsed and those who did not. In contrast, Crane et al. (2014)

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correlation (R) of .85 to a binomial effect size. They demonstrated that using *only* investigator allegiance they could predict the successful treatment 92.5% of the time.

reported that those who practiced on three or more days per week (50% of the curriculum recommendation) were half as likely to relapse to depression at 12-month follow-up compared to those who practiced less frequently. Likewise, in Speca et al. (2000) where 83% of participants achieved the 45 minutes/6 days per week, individual practice predicted mood and accounted for 15% of the variance in mood scores.

Despite the relation between practice and outcome, it is not necessarily the case that "more is more". In a healthy sample, for example, years of meditation experience did not predict effect size across 17 studies (r = .39, p =.06), nor did length of study-based mindfulness (vs. conventional controls k = 27, r = .12, p =.28; vs. active controls k = 16, r = .11, p =.34; Sedlmeier, Loße, & Quasten, 2018). Parsons et al. (2019) also noted that across 28 studies, the dose–response relation between individual practice and outcomes was not linear. This lack of linearity is not uncommon in psychological interventions. For example, in an unguided web-based intervention based on cognitive behavioural therapy and interpersonal therapy for people with depression and cardiovascular disease, high-level use was beneficial, whereas medium-level use offered little benefit over and above low use (Donkin et al., 2013). Clearly, assumptions of a linear dose–response association may be too simplistic, and further models and variables need to be explored to adequately understand the association.

Echoing the concerns of other researchers, at this stage it is unclear how much mindfulness practice is required to achieve optimal effects (Davidson & Dahl, 2018; Van Dam et al., 2017), but it does seem that individual practice beyond the classroom is an important component of effective MBI. It also seems that 45–60 minutes of individual practice six times per week may be beyond the scope of many practitioners. This finding suggests a strong case for the development of brief and self-guided mindfulness-based interventions.

Brief mindfulness inductions

Current evidence suggests that brief mindfulness inductions can have positive effects on a number of psychological outcomes such as anxiety and depressive symptoms (Howarth, Smith, Perkins-Porras, & Ussher, 2019; Schumer, Lindsay, & Creswell, 2018). For instance, in a recent systematic review of brief MBIs (sessions lasting 30 minutes or less for a maximum

of 100 minutes per week for 4 weeks), over 90% of the 85 single-session (k =74), laboratory-based studies (k = 82), involving both clinical (k = 19) and non-clinical populations reported significant positive effects of brief MBI on the measured outcomes (Howarth et al., 2019). These outcomes were broadly health related. Over half of the studies measured mood (k = 48) and mindfulness (k = 47); 30 measured anxiety; and 15 measured depression. Almost half of the studies that measured a psychological outcome – including (in order of most to least frequent) pain (their categorisation), mood, anxiety, depression or other – reported improvements on all outcomes.

Despite Howarth et al. (2019) reporting that the majority of studies were methodologically adequate to robust, only three studies had a low risk of bias. Given that Howarth el al. (2019) also reported that 83/85 studies had an unclear risk of bias, it is apparent that the numbers don't add up, which suggests this review should be interpreted with caution. Howarth et al. (2019) concluded that the aforementioned studies provide support for the idea that MBI practice for as little as five minutes in a single session can positively impact some psychological health outcomes in both clinical and non-clinical populations.

In another recent meta-analysis of 65 brief MBI (N = 5489, predominantly novice meditators), there was a small but significant effect on negative affectivity (g = .21, p< .001; Schumer, Lindsay, & Creswell, 2018). Here, negative affectivity referred to a number of state or trait negative emotional terms, including anger, anxiety, depression, distress, irritability, sadness, shame, stress etc. As in Howarth et al. (2019), the majority of these studies were laboratory-based mindfulness inductions (k = 54, n = 4607). The methodological rigour in the included studies was low, but so too was the data abstraction by the meta-analysts. For example, group descriptive statistics were estimated from ruler measurements where numerical data were not available but bar graphs were provided. Similarly, when condition numbers were not presented (an indicator of the low reporting quality of the original studies), the meta-analysts estimated an even split N. Even so, these brief (primarily single-session induction-based) MBIs were associated with small effects, but the effects only held when the follow-up was immediate (k = 77, n = 6218, g = .29, p <.001) or within one day of the

intervention (k = 23, n = 1483, g = .18, p <.05). When follow-up was later than one-day post intervention, brief MBIs were not associated with significant changes in negative affectivity (k = 5, n = 439, g = .08, n.s.). After accounting for publication biases the overall effects moved from g = .21, to g = .04.

Other brief and self-directed interventions

The evidence for the effectiveness of brief MBIs, although sparse, is more promising outside of laboratory-based mindfulness inductions. For example, a group of nurses who took part in a four-week version of MBSR (n = 14) reported feeling more relaxed and satisfied with their life, and experienced less burnout compared to waitlist controls (n = 16; Mackenzie, Poulin, & Seidman-Carlson, 2006). Similarly, student participation in a five-week version of MBSR (n = 72) was associated with improvements in mindfulness and self-compassion, but not anxiety, compared to a parallel control group (n = 47; (Bergen-Cico, Possemato, & Cheon, 2013). In another study, university staff who undertook a six-week version of MBSR (with reduced class length [one hour] and individual practice [20 minutes]; n = 24) reported lower stress, higher mindfulness and better sleep (Klatt, Buckworth, & Malarkey, 2009). All of these studies had extremely small sample sizes or were quasi-experimental (Bergen-Cico et al., 2013).

Perhaps a stronger form of supporting evidence for the effectiveness of a brief MBI is found in meta-regression and sub-group analyses included as part of broader meta-analyses. For instance, in a meta-analysis of MBI for psychological distress in working adults (k = 19 [9 RCT; 10 other design]; N = 1139), there was no statistically significant difference between brief and traditional MBSR (Virgili, 2015)**.** Other examples of broader meta-analyses that provide support in this manner include Blanck et al., 2018 and Hofmann, Sawyer, Witt, & Oh, 2010.

Emerging evidence also suggests that mindfulness can be learnt by self-help (i.e., with no or minimal support from a therapist; Cavanagh, Strauss, Forder, & Jones, 2014). In a recent meta-analysis of 15 (primarily online) RCTs, self-directed mindfulness and acceptance interventions were associated with small to medium effects on anxiety, depressive symptoms,

and mindfulness or acceptance when compared to controls (anxiety: SMD -.33, 95%CI [-.56, -.10], n = 676, 672, k = 13; depressive symptoms: SMD -.37, 95%CI [-.56, -.18], n = 665, 565, k = 13; and mindfulness or acceptance: SMD: .49, 95%CI [.23, .76], n = 610, 599, k = 10; Cavanagh, Strauss, Forder, & Jones, 2014).

Given the promising, albeit weaker effects of individual practice, brief, and self-directed interventions on mental health outcomes, it is perhaps unsurprising that MBIs are being adapted for and delivered in digital and online formats.

1.3.4. What are the effects of online mindfulness-based interventions?

Following the relative success (and demonstrable effectiveness) of online interventions for mental health (e.g., meta-analyses for depressive symptoms: vs. controls: g = .38, 95%CI [.24, .52], p<.001, N = 3414, k = 22, Firth et al., 2017; anxiety: vs. controls: g = .33, 95%CI [.17, .48], p <.01, N = 1581, k = 9, Firth et al., 2017), and growing evidence for individual practice, brief, and self-directed MBI, attention has recently turned to online mindfulness-based interventions. But, the evidence for online mindfulness-based interventions is still in its early stages and primarily comprises pilot, feasibility, or smaller n studies. Even so, these early studies have reported promising evidence and have become the topic of a number of recent meta-analyses (e.g., Cavanagh, Strauss, Forder, & Jones, 2014; Fish, Brimson, & Lynch, 2016; Jayawardene, Lohrmann, Erbe, & Torabi, 2017; Lyzwinski, Caffery, Bambling, & Edirippulige, 2018; Sevilla-Llewellyn-Jones, Santesteban-Echarri, Pryor, McGorry, & Alvarez-Jimenez, 2018; Spijkerman, Pots, & Bohlmeijer, 2016). In the following paragraphs I will summarise the magnitude and direction of effect found in these meta-analytic reviews before paying closer attention to a more recent, and methodologically rigorous, RCT that is not included in any of the aforementioned meta-analyses (Querstret, Cropley, & Fife-Schaw, 2018).

In one meta-analysis, although online MBIs were not the target intervention, the majority of studies that were included in the analysis were online MBIs (k = 8/15; Cavanagh, Strauss, Forder, and Jones' 2014). Although the number of online studies was too small to

conduct subgroup analyses for this particular meta-analysis, over half of the online MBI studies reported positive findings. More specifically, the standardised mean differences (SMD; and SMD 95%CI) of these studies favoured the intervention over the control in 3/5 studies for mindfulness and acceptance outcomes, 3/6 studies for depressive symptoms, and 3/5 studies for anxiety symptoms. SMDs ranged from a negligible -.02 (Gluck & Maerker, 2011) to much a stronger -.79 effect (Hesser et al., 2012).

Building on this meta-analysis, several more recent meta-analyses have focused exclusively on online MBIs. In a meta-analytic review including 15 online MBIs (N = 2360) in both clinical (e.g., adults with anxiety) and non-clinical populations, online MBIs were associated with several notable improvements in mental health (Spijkerman, Pots, & Bohlmeijer, 2016; three of the included studies were also present in Cavanagh et al.'s [2014] meta-analysis). When only including medium and high-quality studies, pre-post effects of online MBIs on depression, anxiety, stress, well-being, and mindfulness ranged from g = .21 (95%CI [.03, .40], p <.05) in anxiety, to g = .40 (95%CI [.20, .59], p <.001) in stress, as compared to controls. Although this meta-analysis was underpowered to analyse the long-term effectiveness of online MBIs, two of the included studies reported that effects were maintained up to one-year from baseline (see: Hesser et al., 2012; Pots et al., 2016). Spijkerman et al., (2016) – who noted that their analyses were underpowered – provided subgroup analyses split by clinical and non-clinical populations. Consistent with findings from broader MBI meta-analyses (e.g., Khoury et al., 2013), these analyses indicated that the effects of online MBI on depression, anxiety, and well-being were only apparent in clinical populations (see Table 1.2. for specific effects).

Recognising that MBIs affect clinical and non-clinical populations differently, two further meta-analyses of online MBIs warrant attention. First, eight RCTs in healthy populations were identified in a meta-analysis of preventive online MBIs for stress and mindfulness (Jayawardene, Lohrmann, Erbe, & Torabi, 2017; N = 1035). While the cumulative effects of these online MBIs on anxiety (g =.43, 95%CI [.21, .67], p = .0002, N = 1032, k =8) and mindfulness (g = .28, 95%CI [.15, .40], p <.0001, N = 1035, k = 8) were

statistically significant, all but two of these studies were already included in Spijkerman et al. (2016). The two unique studies included a small pilot in older adults (Wahbeh, Goodrich, & Oken, 2016) and a small four-arm RCT trial (Allexandre et al., 2016). Allexandre et al. (2016) recruited 161 workers from a call centre to take part in a four-arm RCT. In this trial, eight-week online MBIs were delivered alone, with group support, or with group and clinical support, and were compared to a waitlist control. Compared to the waitlist control, online MBIs were associated with moderate to large improvements in stress immediately post-intervention (8-weeks: MBI vs. WL: d = .7, p = .008, n = 55; $MBI_{support}$ vs. WL: d = 1.2, p < .0001, n = 51) and at follow up (16-weeks: MBI vs. WL: d = .6, p <.05 n = 47; $MBI_{support}$ vs. WL: d = 1.0, p = .0003, n = 40). Consistent with previous research, MBI with group support was more effective than MBI alone (although the small n means these results should be interpreted with caution).

Second, Sevilla-Llewellyn-Jones, Santesteban-Echarri, Pryor, McGorry, and Alvarez-Jimenez (2018) identified 12 trials in a meta-analysis of online MBIs for people with a clinical diagnosis of depression, anxiety, or bulimia (N = 919; 10 RCT and two uncontrolled trials; the two trials already included in Spijkerman et al. were: Boettcher, Rozental, Andersson, & Carlbring, 2014; Ly et al., 2014). Sevilla-Llewellyn-Jones, Santesteban-Echarri, Pryor, McGorry, and Alvarez-Jimenez (2018) analysed the accumulated evidence as a whole, but also as a function of diagnosis. There was considerable heterogeneity in these interventions and the included studies had small sample sizes (N = 13, Gershkovich, Herbert, Forman, & Glassman, 2016 to N = 52, Dahlin et al., 2016). In only three of the included studies did researchers report collecting data about adverse events, one of which was related to the intervention (participant distress during body scan; Murray et al., 2015). Nevertheless, online MBIs were associated with improvements in both depressive and anxiety symptoms (depressive symptoms: g = -.61, 95%CI [-1.03, -.19] p = .004, N = 656, k = 9; anxiety symptoms: g = -.43, 95%CI [-.73, -.14] p = .004, N =756, k = 10), however, these effects differed by clinical diagnosis. That is, online MBIs were effective for people with a diagnosis of anxiety, but not for those with depression. In the groups diagnosed with depression, the nonsignificant effect on depressive symptoms

seemed to be driven by intervention heterogeneity; only mindfulness-integrated therapies (e.g., ACT) were effective. Similarly, in the groups diagnosed with depression, there was a nonsignificant effect on anxiety symptoms. In contrast, mindfulness-integrated therapies (e.g., ACT) were effective across both diagnoses. Further, although these analyses were underpowered, online MBIs were only effective when compared to a waitlist control; there was no statistically significant difference when compared to TAU or active controls.

Finally, looking more closely at a recent and very rigorous randomised waitlist-controlled trial (RwCT) that was not included in any of the aforementioned meta-analyses. In this RwCT, 118 adults from the general, non-clinical population trailed an online MBCT course run by the Mental Health Foundation in the United Kingdom. The course follows the traditional eight-week MBCT class curriculum but is pre-recorded and delivered online. In this study, participants were asked to complete the course in four weeks (M = 6-weeks, max = 12 weeks). In accordance with best practice, data were analysed following an intention-to-treat (ITT) protocol (with multiple imputation where data were missing). Relative to a waitlist control, online MBCT was associated with large improvements in depression (d = -1.06, 95%CI [-1.22, -.67], p<.001), anxiety (d = -1.09, 95%CI [-1.47, -.98], p<.001), and stress (d = -1.25, 95%CI [-1.64, -.85], p<.001). The odds of participants in the waitlist reporting moderate or severe depression or anxiety were over six times higher than the odds in online MBCT participants. Importantly, when the waitlist received the online MBCT intervention, they too reported within-group changes consistent with the intervention group at all follow-up time points (post intervention, three months, and six months).

In summary, evidence for online MBIs is growing but current research is characterised by a reliance on small sample sizes, waitlist-controlled designs, and high survey and intervention attrition. Online MBIs appear to have small to moderate effects on depression, anxiety, and stress, but further research is required to establish the effectiveness of these interventions.

1.3.5. What are the mechanisms at play in mindfulness-based interventions?

It is remarkable that after decades of psychotherapy research, we can not provide an evidence-based explanation for how or why even our most well studied interventions produce change.

(Kazdin, 2007, p. 23)

Identifying the mechanisms behind mindfulness—how it works—is important for a number of reasons (Kazdin, 2007). Understanding the mechanisms lends validity to mindfulness-based interventions as a therapeutic treatment option, and allows interventions to be optimised. It also assists with identifying other populations or outcomes that may be affected by the intervention, and makes implementation in real-world conditions easier (Kazdin, 2007).

Although a growing body of research demonstrates that mindfulness-based interventions are associated with promising therapeutic effects, the lack of evidence for any mechanisms is one of the most frequently cited limitations of mindfulness-based interventions. Here, I will highlight the most prominent theoretical accounts of the mechanisms of mindfulness meditation, and describe the supporting meta-analytical evidence.

Prevailing theories

Several theories, models, and frameworks have been proposed to explain how mindfulness and mindfulness-based interventions work; these are presented in Table 1.3.

Table 1.3.

Some prevailing theories, models, or frameworks that describe the mechanisms of mindfulness

Author/s	Theoretical Mechanisms
(Benson, 1975)	Relaxation
(Baer, 2003a)	Relaxation, exposure, cognitive change, self-management, acceptance
(Shapiro, Carlson, Astin, & Freedman, 2006)	Metamechanism: Reperceiving (through: attention, intention, attitude). Additional mechanisms: self-regulation and self-management; values clarification; cognitive, emotional, and behavioural flexibility; and exposure
(Hölzel et al., 2011)	Enhanced self-regulation: attention regulation, body awareness, emotion regulation (reappraisal; exposure,

	extinction, and reconsolidation), change in perspective of the self
(Creswell & Lindsay, 2014)	Stress-buffering
(Tang, Hölzel, & Posner, 2015)	Enhanced self-regulation: attention control, emotion regulation and self-awareness
(Lindsay & Creswell, 2017)	Monitor and Acceptance Theory: attention monitoring and acceptance

The earliest clinical theory of mindfulness is outlined in the "Relaxation Response" (Benson, 1975). As mentioned earlier in the *Brief History of Mindfulness*, Benson's relaxation response was a clinical interpretation of meditation that made the practice more acceptable to secular populations (Boals, 1978). According to Benson, meditation activates the parasympathetic nervous system; the associated relaxed mental state assists with recovery from stress-related illnesses (Benson, 1975). Psychophysiological data are consistent with this notion: meditation is often associated with physiological changes that are typical of relaxation, including reduced heart rate, blood pressure, and oxygen consumption (Shapiro & Walsh, 2009). In contrast, some forms of meditation produce a state of arousal, rather than a state of relaxation and are still associated with benefits (Amihai & Kozhevnikov, 2014; Britton, Lindahl, Cahn, Davis, & Goldman, 2014). Lutkajtis (2019) suggests that equating meditation to relaxation is problematic and may explain why some people have unrealistically positive expectations about meditative practice. Someone who is new to meditation and who experiences arousal instead of relaxation may believe they are meditating incorrectly—which could result in under-reporting of adverse effects by practitioners (another common limitation of mindfulness research) (Lutkajtis, 2019). Given that benefits occur with both relaxation and arousal, clearly, the idea of relaxation as the sole mechanism of meditation is incomplete.

Baer (2003) is another proponent of relaxation as a key mechanism of mindfulness. Drawing on earlier work by Kabat-Zinn (1982) and Linehan (1993), Baer reviewed the existing research to propose several theoretical mechanisms, including: relaxation; exposure (attending directly to pain until you are able to do so nonjudgmentally, automatically, and with reduced emotional response); cognitive change (recognising that thoughts do not equate to reality); and awareness (as a way to increase adaptive coping skills and self-management of

symptoms). Baer's (2003) review was a turning point for research on the mechanisms of mindfulness. Subsequent researchers adapted and refined Baer's proposed mechanisms (although not all acknowledge these origins), using different language to describe the same or similar mechanisms.

Most of the remaining theoretical models of mindfulness can be considered within a framework of self-regulation or attention. For example, Hölzel et al. (2011) used neuropsychological research to propose several mechanisms under the umbrella of "enhanced self-regulation"; these mechanisms included attention regulation, body awareness, emotion regulation (reappraisal; exposure, extinction, and reconsolidation), and change in perspective of the self. Tang, Hölzel, and Posner (2015) further refined these ideas in 2015 as enhanced self-regulation through attention control, emotion regulation, and self-awareness.

The model developed by Shapiro et al. was informed by three components thought to make up mindfulness: attention, intention, and attitude. These components are said to underpin the overarching mechanism—reperceiving—which refers to a shift in perspective (Shapiro et al., 2006). Reperceiving is analogous to decentering, another term used regularly in psychotherapy; it is related to the self-regulation frameworks and it is thought to be implicated in an additional series of mechanisms: self-regulation and self-management; values clarification; cognitive, emotional, and behavioral flexibility; and exposure. Building on these theories involving self-regulation, a recent meta-analysis of mindfulness induction studies (in laboratory settings; k = 27) on self-regulation provides some support for the idea that mindfulness practice enhances the regulation of negative affect (k = 15, d = -.28) through attentional control (Leyland, Rowse, & Emerson, 2019).

The stress-buffering model of mindfulness (Creswell & Lindsay, 2014) offers an alternative account of its effectiveness. In this biological model, mindfulness buffers stress appraisals and lowers stress-reactivity, which results in stress reduction. These stress reduction (or "stress resilience") effects are thought to explain how mindfulness affects health outcomes. An important component of this model is the idea that mindfulness-based

interventions should only be effective for clinically unwell people. The authors provide preliminary evidence for the stress-buffering model, but it is too early yet to test the stress–health links.

Another recent addition by Lindsay and Creswell is the Monitor and Acceptance Theory of mindfulness (Lindsay & Creswell, 2017). This theory proposes that two core components of mindfulness practice—monitoring attention and practising acceptance—are the primary mechanisms through which mindfulness meditation practice impacts health outcomes. According to this theory, monitoring of attention enhances present-moment awareness and thus improves selective and executive attention networks; practising acceptance changes the way we react to the present moment and thus improves emotion regulation. In combination, the two components are thought to improve affective, stress, and health outcomes. Lindsay and Creswell recently reviewed preliminary supporting evidence of this new theory (2017).

Further evidence for the mechanisms of MBI comes from a recent systematic review and meta-analyses of MBSR and MBCT interventions that included mediation analyses (Gu et al., 2015). Gu et al. identified 20 MBSR or MBCT studies (k = 15 RCTs, 5 quasi-experimental) of clinical populations that reported a mediation test. Where possible, these mediation analyses were synthesised using two-stage structural equation modelling (Cheung & Chan, 2005). In doing so, they found moderate and consistent evidence that mindfulness, rumination, and worry are mechanisms underlying the association between MBSR/MBCT and psychological outcomes. Further, they found preliminary, but insufficient, evidence for psychological flexibility, self-compassion, and cognitive and emotional reactivity as mechanisms.

Intervention non-specific factors are an overlooked class of (potential) mechanisms that likely impact the association between MBI and mental health outcomes. Intervention non-specific factors are factors common to all interventions, which do not reflect the active components of the intervention. Of these, therapeutic alliance and group effects are among the most widely discussed. Therapeutic alliance refers to the quality of the relationship between

the patient and therapist (which may extend to the student/teacher, or the participant/researcher).

Support for therapeutic alliance and group effects as mechanisms is linked to a broader area of research on non-specific factors in all psychotherapies. Often termed the "dodo bird conjecture"[16], there is extensive support for the notion that all psychotherapies have approximately the same "effectiveness" (Flückiger, Del Re, Wampold, & Horvath, 2018; Luborsky, 1975; Wampold et al., 1997). A meta-analysis of 31 studies looking at the effect of non-directive supportive therapy (NDST)[17] for adult depression revealed that factors specific to the intervention only accounted for around 17% of overall improvement (NDST vs. active intervention), whereas non-specific factors accounted for almost 50% (NDST vs control) and extra-therapeutic factors accounted for 33% (the improvement found in waitlist and TAU control groups; Cuijpers et al., 2012). Further support is evidenced by growing research demonstrating that therapeutic alliance is a strong predictor of intervention outcomes (Flückiger, Del Re, Wampold, & Horvath, 2018). For example, data from the NIMH Treatment of Depression Collaborative Research Program indicated that therapist effects accounted for 8% of the variance in mental health outcomes in patients, whereas treatment type (interpersonal therapy or CBT) accounted for 0% (Kim, Wampold, & Bolt, 2006). Looking more closely at the mindfulness literature, in a small (n = 37: mindfulness arm only) mindfulness-based smoking cessation programme, Goldberg, Davis, and Hoyt (2013) found that therapeutic alliance did not predict primary smoking outcomes but it did predict improvement in emotion regulation, mindfulness, negative affect, and treatment compliance. Likewise, Bowen and Kurz (2012) found short-term effects of therapeutic alliance on self-

[16] Reference to the dodo bird in Lewis Carroll's *Alice in Wonderland* ("At last the Dodo said '*Everybody* has won, and *all* must have prizes'"; p.412) was first used by (Rosenzweig, [1936] 2002), as a metaphor to support the idea that common factors (e.g. therapeutic alliance) were responsible for the efficacy of psychotherapy. Later systematic reviews and meta-analyses (e.g. Luborsky, 1975; Wampold et al., 1997) have reinforced this notion and the term "dodo bird conjecture" or "dodo bird verdict" has held.

[17] NDST is an interesting and unstructured treatment option in which a therapist does not use any formal therapeutic techniques "beyond active listening and offering support, focusing on the participants' problems and concerns" (Cuijpers et al., 2012, p.281). NDST has been used as a treatment arm in a number of trials to control for interventions non-specific factors.

reported mindfulness at two months post intervention, but not four months post intervention. Similarly, in patients with social anxiety disorder, therapeutic alliance predicted clinical symptom severity at post-intervention, six months, and 12 months post-treatment in MBSR (*n* = 40) but not CBT (*n* = 46; (Jazaieri, Goldin, & Gross, 2018). Therapeutic alliance may also occur in digital interventions between the app and the user, although this is not yet well understood (Henson, Wisniewski, Hollis, Keshavan, & Torous, 2019). Group effects may be equally important to MBSR and MBCT, as these are, by design, group-based therapies. Imel, Baldwin, Bonus, and MacCoon (2008) analysed the group effects of 606 participants across 59 MBSR groups and found that 7% of the variance in outcomes was attributed to the group effect.

Outside of mindfulness-based interventions, the important role of intervention non-specific factors is especially clear when we consider that receiving an intervention (as compared to not receiving an intervention) only accounts for about 13% of the variability in outcomes (Wampold, 2013). But intervention non-specific factors have not been prioritised during study design. The ad hoc way in which researchers have included non-specific factors means that although these factors are clearly important, statistical evidence does not yet support their causal role in intervention outcomes (Kazdin, 2007).

In sum, several theoretical models explain the mechanisms behind mindfulness-based interventions, but while supporting evidence for some is growing (e.g., self-regulation and attentional control: Leyland et al., 2019; mindfulness, rumination, and worry: Gu, Cavanagh, & Strauss, 2018) others have little data to support them. On the basis of the current theoretical and experimental literature, self-regulation and trait mindfulness are strong mechanistic candidates.

1.3.6. Adverse effects and the safety of mindfulness-based interventions

On the surface, practicing mindfulness meditation would appear to be innocuous and benign (e.g., you're sitting in silence, focusing on your breathing, and being aware of your

thoughts and feelings), but it can have undesirable effects. From a historical and religious perspective, the undesirable effects are well known; they are better understood as part of normal meditative experiences and have been termed "The Dark Night of the Soul", "Kundalini Crisis", and "Spiritual Emergence" (Lindahl, Fisher, Cooper, Rosen, & Britton, 2017; Lutkajtis, 2019). Early practitioners and researchers cautioned that meditation may be contraindicated for people with obsessive-compulsive and ruminative tendencies (Ellis, 1984; Lazarus, 1976). Further, they suggested that negative side effects of therapeutic meditation may include depression, agitation, and suicidal ideation. Although some early practitioners and researchers (e.g., Ellis, 1984; Lazarus, 1976) raised concerns about the safety of meditation (but not specifically mindfulness), these sometimes adverse effects are only beginning to receive research attention within psychotherapy, secular, and clinical settings (e.g., Lindahl, Fisher, Cooper, Rosen, & Britton, 2017). Understanding the potential for adverse effects is important because the recent popularity of mindfulness means there are large numbers of new practitioners trying mindfulness and their practice is not being supported by trained teachers with adequate experience to support them through these potentially negative experiences such as discomfort, agitation, and anxiety (Lutkajtis, 2019; Van Dam et al., 2017).

When I originally embarked on this thesis, the USA's National Institute of Health (NIH) deemed meditation safe for healthy people with the caveat that "There have been rare reports that meditation could cause or worsen symptoms in people who have certain psychiatric problems, but this question has not been fully researched" (National Center for Complementary and Integrative Health, NIH, 2015). Subsequent popular media stories have anecdotally reported that intensive meditation (although not specifically mindfulness meditation) can result in psychological harm (e.g., Rocha, 2014; Foster, 2016). Several case studies and observational studies have also reported serious and distressing meditation-related experiences including increased stress and depression (Dobkin, Irving, & Amar, 2012; for overview see Lutkajtis, 2019; Van Dam et al., 2018).

When I first proposed these studies, only one prospective study to my knowledge had reported negative effects of meditating[18]. In Shapiro's (1992) study, 27 long-term meditators (*M* = 4.27 years meditation experience) were on an intensive two-week or three-month meditation retreat (meditating for a minimum of 10 hours a day). At least one adverse effect was experienced by 62.9% (*n* = 17) of the meditators, and 7.4% (*n* = 2) experienced profound adverse effects. Shapiro's study illustrates the 'dark side of meditation' (e.g. Foster, 2016); however, Shapiro (1992) noted that those who had meditated the least also experienced the fewest adverse effects, and the adverse effects were considered by the meditators to be part of the normal process of meditating. Some examples of the adverse effects included "increased awareness of negative qualities and emotions within myself" (Shapiro, 1992, p. 64), increased disorientation, boredom, addiction to meditation, more judgemental of others, "false" superiority, discomfort with current friends, and hypersensitivity to the city environment. In a second publication using the same sample, Shapiro (1992) reported that the valence of thoughts (positive or negative) before practising was associated with the likelihood of experiencing adverse events; that is, if the meditator reported feelings of apprehension and "fear [that the retreat] is more than [I] can handle" before the retreat, they were more likely to have an adverse experience (Shapiro, 1992, p. 31).

More recently, Lindahl et al. (2017) interviewed experienced Buddhist meditators (with a minimum practice history of 18 years; excluding users of meditation apps) about meditation-related challenges. Although the average onset of challenging or difficult experiences was after 7.1 years of practice, almost one-third (29%) reported that challenging experiences occurred within the first year of practice. Further, at the time of these challenging experiences, one-quarter of meditators were practicing for only 30–60 minutes per day, suggesting that it is plausible that even brief mindfulness meditation may result in adverse experiences. Similarly, in an online survey of meditators (with meditation experience longer than one month), one-quarter of respondents (*n* = 87/342) reported an unwanted experience

[18] I contacted Prof. Shapiro via email about adverse experiences and he provided me with a copy of the articles discussed here and a publication of one of his case studies that reported no adverse effects.

(Cebolla, Demarzo, Martins, Soler, & Garcia-Campayo, 2017). Most events occurred during individual practice and in meditations that were 20 minutes or longer; involved anxiety symptoms, depersonalisation or derealisation; were transitory; and did not require the discontinuation of meditation.

In a recent systematic review of MBSR and MBCT studies that included an 'adverse events' statement, Wong, Chan, Zhang, Lee, and Tsoi (2018) identified 36 RCTs (25 MBSR, 11 MBCT, N = 4031; from 7931 search records). Across these 36 studies, there were a total of 19 adverse events in participants from mindfulness conditions and 19 adverse events in participants from control conditions; a rate of less than 1%. In MBSR trials, no *serious* adverse events were recorded; three trials reported at least one adverse event (e.g., anger, anxiety, pain, and neck strain). In two MBCT trials, 10 serious adverse events were recorded. These serious adverse events included hospitalisations for physical health issues and overdose, and three non-fatal and two fatal cases. Importantly none of these serious adverse events were attributed to the intervention (as judged by an independent committee). Overall the rate of adverse events was low (1%) relative to other psychotherapies (approximately 5–10%; Crawford et al., 2016; Lilienfeld, 2007). The authors concluded that MBSR and MBCT are relatively safe. But, the low rates of adverse events may simply reflect a lack of recording rather than a lack of occurrence.

Lutkajtis (2019) recently suggested that one reason that clinical researchers have overlooked measuring adverse experiences is simply because meditation has been seen as a successful therapy, and "successful therapeutic interventions are supposed to help, not harm" (Lutkajtis, 2019, p. 200). Another reason may be that measuring adverse experiences is not simple when little is known about them. Beyond Lindahl et al.'s (2017) list of challenging experiences, there is little research on the topic for other researchers to apply to their own work. Paradoxically, sparse knowledge about adverse effects creates a challenge for researchers wishing to monitor these events. For this reason, some academics have publicly raised the topic to challenge their academic and clinical peers to more carefully consider the

issue of risk and to report adverse events where they occur (Davidson & Dahl, 2018; Dobkin et al., 2012). Others have echoed these concerns, specifically in regards to self-directed mindfulness apps (Tlalka, 2016; interviewing Zindel Segal).

Taking the aforementioned research into consideration, it is clear that not only is it possible to have an adverse experience related to mindfulness meditation practice, but it is also perhaps quite a normal (albeit unpleasant) experience. Both experienced and new meditators can have challenging or adverse effects when practising. For some, these experiences will have long-term and serious implications (e.g., Lindahl, Fisher, Cooper, Rosen, & Britton, 2017; Wong, Chan, Zhang, Lee, & Tsoi, 2018), while for others they may simply be unpleasant, but transitory (e.g., Cebolla, Demarzo, Martins, Soler, & Garcia-Campayo, 2017; Shapiro, 1992). For any intervention, it is necessary to distinguish between temporary discomfort that is a normal part of psychological treatment (e.g., confronting challenging experiences and applying new skills), and lasting or severe harm related to the intervention. In a blog post for the Oxford Mindfulness Centre, Baer and Kuyken (2016) argued that the intensity of the practice, the vulnerability of the practitioner, and the quality of the instruction are all key points to consider when recommending mindfulness as a practice. They maintain that until the risks are better understood, those interested in mindfulness should begin with low to moderate-intensity practices (e.g., self-help or app-based mindfulness: low intensity; MBSR: moderate-intensity).

A challenge for future researchers is to find a way to monitor these experiences and to delineate normal challenges associated with psychotherapy from more serious adverse events. An interim solution is to continue to monitor the direction of mental health changes, to recommend participants desist practice and see their health professional if their practice results in negative experiences, and to provide participants with ample opportunity to provide feedback on their experiences (including by using checklists of common side effects; Bent, Padula, & Avins, 2006). Recognising that further caution is warranted, the NIH statement has now been updated to reflect that meditation may be less safe than initially anticipated: “There

have been rare reports that meditation could cause or worsen symptoms in people with certain psychiatric problems like anxiety and depression. People with existing mental health conditions should speak with their health care providers before starting a meditative practice, and make their meditation instructor aware of their condition" (National Center for Complementary and Integrative Health, NIH, 2018).

Although there is some evidence from advanced meditators (i.e., those with a minimum of 18 years of meditation experience; Lindahl, Fisher, Cooper, Rosen, & Britton, 2017) that challenging experiences can occur even during brief meditations, the weight of the anecdotal reports and prospective evidence suggests that adverse experiences are more common following intensive and retreat-based practice (e.g., Baer & Kuyken, 2016; Shapiro, 1992). Indeed, eminent mindfulness researchers Baer and Kuyken (2016) have suggested that brief practices (such as those found in online apps) should be considered less risky. Even so, in the absence of direct pastoral care and when MBIs are being self-administered, it may be wise to suggest that practitioners should seek help from a medical professional if they have a negative experience that troubles them.

1.4. The *potential* place for mobile mindfulness meditation in mental health[19]

10-years can be considered a long or short period of time. In the traditional healthcare industry, 10-years is merely the time span for a product development cycle. In the digital arena, 10-years is close to prehistoric.

Research2Guidance (a digital health consulting group), 2017, p. 7

A caveat

When I began my research for this thesis, there were only two experimental studies covering the topic of mobile mindfulness – that is, the use of mobile phones to deliver mindfulness meditation as a mental health intervention (conference abstract: Bostock & Steptoe, 2013, published manuscript: Bostock, Crosswell, Prather, & Steptoe, 2019; and, Howells, Ivtzan, & Eiroa-Orosa, 2016: online first in 2014). In line with the quote above, and consistent with the upward trajectory of mindfulness research in general, the field of mobile mindfulness research has changed swiftly. The original research presented in this thesis (Studies 1 to 3) reflects the research that existed at the time it was carried out. In the spirit of completeness, I have updated this literature review to reflect the burgeoning field of app-based, digital, mobile mindfulness meditation. To that end, in the final section of this literature review, I will summarise and critique the nascent research on mobile mindfulness meditation, noting that some of these publications postdate the research outlined in the empirical portions of this thesis.

1.4.1. Overview and rationale

The relatively recent development of mobile applications (apps) for smartphones presents a promising opportunity to overcome a number of the barriers associated with typical mindfulness meditation training (Cavanagh et al., 2014; Mani, Kavanagh, Hides, & Stoyanov, 2015; Plaza, Demarzo, Herrera-Mercadal, & García-Campayo, 2013). Mindfulness meditation

[19] This section is an updated version of the introduction from the following manuscript: Flett, J. A. M., Hayne, H., Riordan, B. C., Thompson, L. M., & Conner, T. S. (2019). Mobile mindfulness meditation: a randomised controlled trial of the effect of two popular apps on mental health. *Mindfulness, 10*(5), 863-876. doi: 10.1007/s12671-018-1050-9

delivered via a mobile app allows an experienced instructor to deliver high-quality guided meditation training to far more people than face-to-face training can practically allow (Cavanagh et al., 2014). Further, the portable nature of the mobile phone can reduce geographical, social, and financial barriers to access (Cavanagh et al., 2014).

Although there are thousands of mindfulness meditation apps available with, collectively, millions of downloads (Schlagenhauf, 2018), there is a high turnover rate for mindfulness meditation apps in app stores (Larsen, Nicholas, & Christensen, 2016; also see: Bakker, Kazantzis, Rickwood, & Rickard, 2016; on Donker et al., 2013). The relative newness of these apps, combined with the high turnover rate of app technology, means that few studies have rigorously examined the effectiveness of these apps for improving mental health (Mani et al., 2015; Plaza et al., 2013). Given that mindfulness meditation practice is increasingly used in mental health-care settings (Brody, Scherer, Turner, Annett, & Dalen, 2018), and the fact that these apps are promoted as delivering health benefits (e.g., "creating healthier, happier and more compassionate people around Australia and across the globe", Smiling Mind, 2017), the evidence gap is particularly concerning, because people may turn to mindfulness meditation apps in the absence of or in lieu of contact with a health professional.

While researchers are making inroads in testing web-based mindfulness meditation interventions (see: Spijkerman, Pots, & Bohlmeijer, 2016 for review and meta-analysis), the evidence is far more sparse in the app-based mindfulness meditation arena. To my knowledge, at least 14 published studies have tested whether mindfulness meditation apps improve mental health. These studies are reviewed below.

1.4.2. Nascent research on mobile mindfulness meditation

In a randomised, controlled trial, Howells et al. (2016; first available online in 2014) tested the mindfulness meditation app Headspace for 10 days against an attention control app, in a non-clinical adult sample of 121 "self-selected … happiness-seekers" who were recruited to a study that "aimed to enhance well-being" (Howells et al., 2016, p.169). When compared to the attention-matched control group, participants randomly assigned to use Headspace

showed significant improvements in depressive symptoms and positive affect measured after 10 days of app usage; no changes were found for satisfaction with life, flourishing, or negative affect. These findings suggest that using Headspace for 10 days reduces depressive symptoms and improves happiness, albeit over a short period of time and in those motivated to become happier.

In another study, researchers supplied 45 sessions of Headspace to 123 employed adults from the UK (Bostock, et al., 2019). At eight weeks post-baseline, the users reported significant improvements in depressive symptoms, anxiety, global well-being and several measures of job strain compared to a waitlist control group (n = 55). Further, those who had used Headspace more frequently showed greater improvements in psychological outcomes than those who had used the app less frequently. Improvements in well-being and job strain were also sustained at a 16-week follow up. Other studies with smaller sample sizes have also demonstrated some benefit. In a one-arm pilot study, 30 medical residents who were given four weeks of access to Headspace reported higher mindfulness and positive affect when accounting for frequency of app use (Wen, Sweeney, Welton, Trockel, & Katznelson, 2017).

In another small pilot study conducted by researchers from Headspace (and other university-affiliated researchers), researchers recruited a convenience sample of employees from a workplace (to represent the general population) with no previous meditation experience. Employees were provided with 30 days of access to Headspace immediately (n = 38) or after a 30-day wait (waitlist: n = 36; Champion, Economides, & Chandler, 2018). Employees reported their satisfaction with life, perceived stress, and resilience at Day 0, Day 10, and Day 30. Following an intention-to-treat protocol (albeit using an unsatisfactory imputation method, Last-observation Carried Forward, see: Lachin, 2016, for critique), the researchers found that access to Headspace was associated with improvements in satisfaction with life, perceived stress, and resilience at 10 and 30 days as compared to a waitlist control (Champion et al., 2018). In a similar design, Carissoli, Villani, and Riva (2015) compared the use of a 'mindfulness-inspired' meditation app ("it's time to relax") with listening to music or a waitlist control, in 56 employed Italian adults over a three-week period. Both the meditation

app users and the music listeners showed some improvements in coping with psychological stress.

In another recent study conducted by researchers from Headspace (and other university-affiliated researchers), the use of up to 10 sessions of Headspace by 41 adults was associated with a significant improvement in irritability, affect, and stress resulting from external pressure, when compared to 28 adults assigned to a voice-matched audiobook educational attention-control group (Economides, Martman, Bell, & Sanderson, 2018). Similarly, 45 medical students who were randomly assigned to use Headspace for 30 days reported significant improvements in perceived stress over time and improvements in general well-being, when compared to a waitlist control group (Yang, Schamber, Meyer, & Gold, 2018). Finally, in a feasibility study, 15 adults users of the Finnish app Oiva (grounded in Acceptance and Commitment Therapy [ACT] incorporating mindfulness training), showed significant improvements in stress and satisfaction with life following one month of use (Ahtinen et al., 2013).

In another study conducted by a researcher from the popular mindfulness meditation app Calm (in addition to university affiliated researchers), the use of Calm for up to eight weeks by 41 adults was compared to a waitlist control of 47 adults. Here, use of Calm (on average for 38 minutes per week, using objective data) was associated with very strong improvements in perceived stress and mindfulness as compared to waitlist controls (SMD *d*'s 1.24 and 1.11 for stress and mindfulness, respectively; *p*'s <.001). Despite the size of these effects, the interpretation of this study is limited for a number of reasons. Unfortunately, the study had a small sample size, did not follow an intention-to-treat protocol, and retrospectively altered their registered study plan—a detail not mentioned in the publication, but available on the archive of the registration: clinicaltrials.gov/ct2/history/NCT03891810—such that new outcomes were retrospectively added as secondary outcomes in the registry, but are presented as primary on the publication. Despite recruiting fewer participants than their power analysis suggested was necessary, the authors reported that they were adequately powered because their effect sizes were strong. There are three reasons to query this interpretation. First, the

effect size they used to conduct their power analysis (d = .76) is far higher than previous (also underpowered) research would suggest is feasible (i.e., refer to effect sizes from the reviewed meta-analyses; Table 1.2.). Second, basing power calculations on effect sizes from previous research is ill-advised when the previous studies were also underpowered, because this practice leads to inflated effect sizes (see: Schäfer & Schwarz, 2019). Third, while the authors certainly reported strong effect sizes, post-hoc power analyses using observed effect sizes is considered poor practice for a number of reasons that are perhaps best explained by statisticians (see: Gelman, 2019 for a very brief answer). In sum, the aforementioned studies are characterised by a number of limitations including, most commonly, small samples sizes and inappropriate analyses (e.g., inappropriate analysis of pilot data; refer to: Lancaster, Dodd, & Williamson, 2004; Lee, Whitehead, Jacques, & Julious, 2014). For these reasons, caution is warranted when interpreting the reported effects.

More recently there have been several more rigorous trials that were designed to ascertain the effectiveness of mobile mindfulness apps. First, although they used a small sample (N = 91), Noone and Hogan compared Headspace (n = 43) to an app-based, voice-matched, "sham mindfulness" condition (n = 48) where participants participated in breathing exercises. These were referred to as meditation, but no guidance was provided relating to awareness of their body or breath (Noone & Hogan, 2018). All analyses were preregistered, the design has a low risk of bias (i.e., double blinding of participants and researchers during analysis, intention-to-treat analyses), and adherence to the intervention was objectively measured (number of sessions completed provided by Headspace). The authors found that almost 40% of participants completed at least 20 sessions over the course of six weeks. But approximately 30% of participants completed zero sessions, and this rate was slightly lower in Headspace participants (28%) than sham meditation participants (35%), although the authors did not report whether this was statistically different. The researchers found no difference in mindfulness, well-being, or affect between sham meditators and Headspace users. One potential criticism here involves the choice of imputation method; where data were missing, the participant's baseline observation was carried forward (27% of sham participants and 16%

of Headspace participants). This method carries the same risks as Last-observation Carried Forward (see: Lachin, 2016). To my knowledge this is the first example of published null results in app-based mindfulness.

Second, in a randomised waitlist-controlled trial of VGZ Mindfulness Coach (a mindfulness meditation app comprising 40 meditation tracks created by VGZ Health Insurance in the Netherlands), participants recruited from Facebook received weekly automated reminder emails to download and use the VGZ Mindfulness Coach app for five weeks (a programme consisting of 25 brief meditation tracks ranging in length from 2–37 minutes; intervention condition, n = 191), or they were invited to download it following the eight-week post-test survey (wait-list condition, n = 186; van Emmerik, Berings, & Lancee, 2018). Despite high drop-out (41% at 8 weeks and 71% at 20 weeks), using an intention-to-treat analysis, both intervention and waitlist participants reported significant improvements in psychological health at eight weeks relative to their baseline (intervention: SMC = .92, p <.001; waitlist: SMC = .51, p <.001), and some improvement was retained for intervention participants at 20 weeks (SMC = .32, p <.001). Importantly, intervention participants' improvement in psychological health at eight weeks was more modest yet still statistically significant when compared to the waitlist control (SMD = .38, p <.01). Although one of the authors was an employee of VGZ at the time of this study, the authors disclosed this conflict of interest and the trial was preregistered. The results of this study provide some early evidence that mobile mindfulness meditation can have longer-term effects when used under relatively natural conditions, however, the use of a waitlist control, and self-reported adherence, limits the conclusions that can be drawn.

Third, in a small, preregistered trial using a dismantling design, researchers compared 15 smartphone-based sessions lasting for 20 minutes of monitoring and acceptance training, monitoring training only, or coping training (an active-specific control) in 153 stressed adults over the course of two weeks (published across two manuscripts: Lindsay, Young, Brown, Smyth, & Creswell, 2019; Lindsay, Young, Smyth, Brown, & Creswell, 2018). Objective adherence (timestamped completion data) to the interventions was high across all conditions

(approximately 14/15 sessions). Using experience sampling for three days before and after the intervention to assess loneliness and social interactions, in addition to measures of cortisol, blood pressure, and subjective stress reactivity (via a modified Trier Social Stress Test), researchers reported that monitoring and acceptance was associated with reduced cortisol and systolic blood pressure as compared to monitoring only or the coping control (Lindsay et al., 2018). Further, monitoring and acceptance was associated with increased social contact and a 22% reduction in daily-life loneliness as compared to monitoring only or the coping control (Lindsay et al., 2019).

Finally, in an even larger study of adults recruited by email from large institutions in Hong Kong or via online, Facebook, and news media advertisements, a mindfulness-based app (n = 703) was compared to a self-compassion app (n = 705) or to a cognitive behavioural psychoeducation app (n = 753; Mak et al., 2018). App users were provided with four weeks' access to their assigned app, which contained 28 condition-specific sessions that were 10–15 minutes long, in addition to mood tracking, gamification elements (reward badges for session completion), and in-built reminder functions. Across all conditions adherence was around 30% (i.e., approximately nine out of 28 sessions); however, mindfulness-based app users had the lowest completion rates at eight out of 28 sessions, and this was *just* statistically significant (p =.04). Drop-out was very high across all conditions at post-intervention and three-month follow up (post-intervention: N = 1653/2161 drop out, 76.5%; three-month follow up: N = 1812/2161 drop out, 83.9%). Even so, in both intention-to-treat and completer (100% adherent) analyses, app users in all conditions reported significant improvements in well-being and distress from baseline to post-intervention and from baseline to follow up. There were no significant differences in well-being and distress between conditions. Using the intention-to-treat data, mindfulness-based-app users reported small but sustained improvements in well-being and distress at post-intervention and three-month follow-up (SMC d's ranging from -.28 in distress to .42 in well-being). Another important contribution was information about intervention attrition; here, 69% of participants stopped using their mindfulness app after the first week. To my knowledge, this is the only study to compare app-based mindfulness to an

active-specific control. However, because both comparison conditions were active-specific controls, it is impossible to rule out placebo and digital placebo effects.

On the basis of the previous app-based mindfulness research, there may be benefits of app-based mindfulness meditation training, but the conclusions are by no means definitive, and consensus on the effectiveness of mindfulness training remains elusive in the broader mindfulness literature (Van Dam et al., 2017). Of the studies reviewed here, one of the published studies used an app-based attention control (Howells et al., 2016), one used an app-based placebo-control (Noone & Hogan, 2018), one used two app-based active-specific controls (Mak et al., 2018) and another used one app-based active-specific control (Lindsay et al., 2019, 2018) as the comparison condition. The rest have used waitlist, non-app-based attention control, or no controlled comparison conditions, which can only provide insight into whether mobile mindfulness interventions have an impact over and above no treatment. Such designs also do not control for digital placebo effects, that is, the potential for placebo-like non-specific treatment effects in mobile interventions resulting from the high levels of mental and physical attachment, trust, affinity, and reliance on our mobile phones (Clayton, Leshner, & Almond, 2015; Torous & Firth, 2016). Further, many of these studies have been relatively short—i.e., they deliver less than two weeks' mindfulness meditation practice—or they have lacked external validity (e.g., mandated adherence). Given that the end goal of these tools is to provide a training platform to establish long-term mindfulness practice, it would be useful to know whether these apps are effective over longer periods of time. Also, it is important to address whether use of these tools improves mental health under more naturalistic conditions (e.g., when people use the app at their own discretion) and not just under optimal conditions (e.g., when people are requested to use the app for a specific period of time).

1.5. Conceptual and methodological issues in research on mindfulness and meditation

Mindfulness has taken an awful lot of flak lately with critics piling on from all quarters. There seems to be a kind of Thermidorian reaction, a counter-swing of the pendulum, in response to the successful dissemination of mindfulness-based techniques throughout society.

Segall, 2013, para. 1

While evidence for the effectiveness of mindfulness-based interventions is growing, so too is the focus on the conceptual issues of the secular approach to mindfulness, the methodological rigour (or lack thereof) in experimental research, and the critical evaluation of the accumulated evidence related to mindfulness meditation (e.g., Bodhi, 2011; Grossman & Van Dam, 2011; Van Dam et al., 2018). In the following section I highlight several of the conceptual and methodological issues that continue to trouble mindfulness-based psychological research.

1.5.1. Deconstruction, secularisation, and appropriation

Buddhist meditation has been lifted from its traditional setting in Buddhist doctrine and faith and transplanted in a secularized culture bent on pragmatic results.

Bodhi, 2011, p.35

Many scholars, practitioners, and religious leaders have expressed concerns about the contemporary uses of mindfulness (for review, see: Bodhi, 2011; Monteiro, Musten, & Compson, 2015), suggesting that the deconstruction of mindfulness into active components is a form of 'scientific materialism' which is inconsistent with Buddhism (Monteiro et al., 2015). I question this interpretation, given that the Buddha presents his dharma (the *Four Noble Truths*) as a testable hypothesis (Batchelor, 2011; Maex, 2011).

Another concern regards secularisation, and whether it is even possible for meditation (and by association, mindfulness) to be secular (Lutkajtis, 2019). Lutkajtis suggests that the

end goal of the meditative practice distinguishes whether it is religious or secular meditation. However, she then suggests that meditation derived from Kabat-Zinn's approach is secular because it is applied toward clinical goals such as the alleviation of pain, rather than enlightenment (Lutkajtis, 2019), which ignores that the *Four Noble Truths* are concerned with this goal too. Some have described the underlying tension about secularisation as masking the overall concern of appropriation (Lee & Young, 2018; Purser, 2015; Purser & Milillo, 2015; Surmitis et al., 2018).

Concerns have also been raised about the quality of the instructors who deliver secular mindfulness-based interventions (Grossman & Van Dam, 2011; Monteiro et al., 2015; Van Gordon, Shonin, Griffiths, & Singh, 2015). These concerns have some validity (for example, some training programmes have provided certification after an eight-week course; Van Gordon, Shonin, Griffiths, & Singh, 2015). Other scholars have questioned this labelling of secular instructors as inauthentic and provide arguments to suggest that the majority of Buddhist practitioners are likely inauthentic too (Van Gordon et al., 2015). These scholars go on to suggest that the single most important indicator of quality in a mindfulness instructor is that said instructor has 'amassed authentic spiritual and meditative realisation' (Van Gordon, Shonin, Griffiths, & Singh, 2015, p.54). They conclude:

> *... if a teacher of either Buddhism or a secular mindfulness-based approach is sincere in their meditation practice ... then recipients of their teachings—whether in Buddhist or secular (e.g. clinical) contexts—are likely to derive lasting benefit from their participation.*
>
> Van Gordon, Shonin, Griffiths, & Singh, 2015, p. 53

1.5.2. Commodification of mindfulness: The DIY mentality, McMindfulness, and neoliberalism

Rather than applying mindfulness as a means to awaken individuals and organisations from the unwholesome roots of greed, ill will and delusion, it is … being refashioned into a banal, therapeutic self-help technique that can actually reinforce these roots.

Purser and Loy, 2013, para. 6

Other, more scathing, critiques of clinical and secular MBIs stem from the increasing commercialisation of mindfulness as a 'product'. In the most notable example, Ron Purser (a professor of management and Zen Buddhist teacher) and David Loy (a philosopher and Zen Buddhist teacher) penned a popular critique of MBI under the title 'Beyond McMindfulness', published in the *Huffington Post* (2013). In this piece, Purser and Loy lobbed broad criticisms of the corporate and capitalist conceptions of mindfulness, saying that these do not align with Buddhism proper. They provide a clear critique of how neoliberal ideology has shaped contemporary (and particularly corporate) mindfulness, and suggest these contemporary mindfulness programmes strongly resemble the earlier so-called 'cow psychology' corporate movements in the 1950s and 1960s ('contented and docile cows give more milk', para. 16). In these corporate movements, counselling techniques were used to induce unhappy employees to feel their concerns had been heard by management, who then maintained the status quo. According to Purser and Loy, corporate mindfulness 'conveniently shifts the burden onto the individual employee: stress is framed as a personal problem, and mindfulness is offered as just the right medicine to help employees work more efficiently and calmly within toxic environments' (Purser & Loy, 2013, para. 14). Bodhi (2011) also echoes these concerns, claiming that mindfulness is in danger of becoming a perfect supplement to capitalism.

These criticisms are not without merit. Contemporary mindfulness practices are presented as universal practices for stress reduction and self-improvement (e.g., see: Kabat-Zinn, 2013), and the most widely accepted courses often have a hefty price tag (USD$450–600 for MBSR at the Center for Mindfulness; UMASSMed, 2019). Proponents of these courses (e.g., Kabat-Zinn, but others are quoted extensively in Walsh, 2016) suggest the causes of

stress and offer practices for personal alleviation, discipline, and control, rather than attending to the social and institutional systems that generate the stress in the first place. In a discourse analysis of popular books published by Jon Kabat-Zinn, Barker (2014) lays out a solid argument for how mindfulness (as promoted by Kabat-Zinn) contributes to the medicalisation of the self and places the onus of all forms of ill-health directly on the individual.

Secular and clinical applications of mindfulness are also often criticised for lacking explicit ethical values critical to Buddhist mindfulness (Bodhi, 2011; Monteiro et al., 2015). Others disagree, however (e.g., Baer, 2015). Ethical values are inherent in clinical settings because clinicians adopt professional codes of ethics that require them to do no harm. For example, APA requires 'a personal commitment and lifelong effort to act ethically; to encourage ethical behavior by students, supervisees, employees and colleagues; and to consult with others concerning ethical problems' (American Psychological Association, 2002, p.1060). Further, existing MBIs such as ACT include the identification and focus of self-identified values. Baer (2015) suggested it is important for clinical MBIs to prioritise the adoption of the practitioner's values rather than prescribed values: doing so will promote more adaptive and prosocial behaviours. This notion is consistent with self-affirmation theory, self-determination theory, and the self-concordance model, which promote autonomy as key to optimal human functioning.

Concerns have been expressed that, in the absence of clear ethical foundations, mindfulness could be used to promote passive acceptance of unethical business practices, such as oppressive working conditions, or could be used in ways that harm others (Purser, 2018). The provision of mindfulness training in corporate and military settings, for example, has been controversial (e.g., see: Monteiro, Musten, & Compson, 2015). Some scholars contend that it is antithetical to core Buddhist principles to provide mindfulness training to those who may use it to kill (Monteiro et al., 2015), while others contend that restricting access to mindfulness and the *buddhadharma* (the teachings of Buddha) is also antithetical to core Buddhist principles (Van Gordon et al., 2015). These scholars note that the Buddha's teachings are like

an all-purpose medicine: if the learner has the wrong intention (*micchā sankappā*, that is, to use for selfish or negative purposes; recall that right intention [*sammā sankappā*] is part of the Eightfold Path and each has a right and wrong path: Bodhi, 2011), they will gain only a superficial account of the teachings (Van Gordon et al., 2015). When mindfulness is taught correctly, the student becomes more compassionate; when they are taught incorrectly, they are no longer learning mindfulness (Van Gordon et al., 2015).

While these critiques provide a good opportunity to reflect and prioritise change in mindfulness research, the popularity and wide availability of mindfulness-based products (over 2000 mindfulness meditation apps are available in appstores; Schlagenhauf, 2018) suggests that people will continue to meditate no matter what. With this point in mind, and taking an apologist's route, I suggest that it is more important to consider the effectiveness and safety of these widely available products.

1.5.3. Mindfulness is ill-defined and challenging to measure

Mindfulness is paying attention in a particular way: on purpose, in the present moment, and nonjudgmentally.

Kabat-Zinn (2013), para. 4

… or is it?

Jayde Flett

Although there is strong consensus among Buddhist scholars about the definition of mindfulness, it is by no means a closed book (Monteiro et al., 2015; Van Gordon et al., 2015). The Buddha's teachings were shared through oral histories during the first centuries of Buddhism; to facilitate retention of these teachings, they were compressed into simple and repetitive formulas to allow each generation of followers to commit them to memory (Bodhi, 2011). This reliance on oral transference means that there exist between Buddhist traditions many different ways to interpret and contextualise mindfulness (Monteiro et al., 2015; Van Gordon et al., 2015). However, Buddhist scholars do tend to agree that the reductive 'non-

judgmental', 'bare-attention', 'present-moment focus' contemporary definitions of mindfulness are an inadequate and denatured interpretation of a centuries-old spiritual tradition (see: Bodhi, 2011; Dreyfus, 2011; Monteiro, Musten, & Compson, 2015; Purser & Milillo, 2015). Both Bodhi (2011) and Dreyfus (2011) explicitly take issue with the non-judgemental and present-focus definitions favoured by psychotherapeutic researchers. They both discuss how these terms reflect pragmatic and practical instructions, are an operational definition of initial mindfulness that represents only a partial understanding of mindfulness, and indicate a goal of practice at the beginning of one's mindfulness practice. They maintain that the commonly used definitions are divorced from the wider Buddhist canon. But researchers are also not content with the current definitions, and much work has gone into gaining some form of consensus over the definitions (see Van Dam et al., 2017 for a review of these discussions). Kabat-Zinn has admitted that the often-cited definition used at the start of this section is simply a definition of convenience (Van Dam et al., 2017).

Complicating this issue is the growing tendency in clinical research to use the term 'mindfulness' as a catch-all to describe a psychological state of awareness and attention in the present moment, a trait (such as a tendency to process information in a mindful way), or a practice (such as mindfulness meditation). With the increased popularity of mindfulness, the catch-all is now extending beyond research settings and is being used to describe almost anything. Simply Google 'mindful' or 'mindfulness' and you will find any number of products claiming the title, including teas and sex toys. 'Mindfulness' has become a 'floating signifier' – a term with vague, variable, unspecifiable or non-existent meaning, a stand-in for whatever you want to signify (Chandler, n.d., cited in Drougge, 2016). Evidence for vague uses of the term is also apparent on social media: Kraus (2019), for example, recently reported that over 11.8 million, mostly innocuous, Instagram posts use the hash-tag #mindfulness.

The procedural definition of mindfulness often used in clinical research also has implications for the measurement of mindfulness. Self-report data are commonplace in psychological research (Baumeister, Vohs, & Funder, 2007 suggested that up to 80% of social

and personality psychology research relies on indirect assessments like self-report to infer behaviour). Grossman & Van Dam (2011) criticise both the commonly used definitions and the measurement of mindfulness by self-report, saying these overlook other key components of mindfulness from a Buddhist perspective (e.g., the Eightfold Path and the Four Immeasurables, see section 1.1., 500BCE). (This is ironic, since Grossman is an author of a common measure of mindfulness, the Freiburg Mindfulness Inventory, Buchheld, Grossman, & Walach, 2001). They further highlight that self-reported mindfulness questionnaires tap into how people *think* or *believe* they are, which, from the broader literature, is often at odds with how they actually behave (Baumeister et al., 2007).

A related concern is that mindfulness instruction during guided practice and mindfulness questionnaires use a common language. Increases in mindfulness (as measured by self-report questionnaires) may simply reflect increased familiarity with mindfulness terminology (although this remains to be tested). Further, experienced meditators and novice meditators interpret the questions in mindfulness questionnaires differently, which can have detrimental consequences for the construct validity. In one example, binge-drinking students endorsed higher mindfulness scores than experienced meditators who had just completed a meditation retreat (Grossman & Van Dam, 2011).

Finally, there is some evidence that mindfulness interventions, counter-intuitively, do not result in increased self-reported mindfulness (e.g., in a meta-analysis of group-based MBIs, only half of all MBIs resulted in higher mindfulness; Visted, Vøllestad, Nielsen, & Nielsen, 2015). Grossman and Van Dam (2011) concluded that, given the limitations in the measurement of mindfulness, researchers should consider other ways of quantifying mindfulness-skills. One suggestion was that because one goal of mindfulness practice is to alleviate suffering, outcome measures in MBIs should assess reductions in suffering. This suggestion has also been reiterated by Van Dam et al. (2017), who go on to provide several further suggestions to improve mindfulness research. For example, they urge researchers to explicitly differentiate the mental states and processes that are taught, practised, and

investigated. They also stress that if researchers do use a self-reported scale of mindfulness, they should explicitly identify the aspects their chosen scale claims to measure. Finally, they strongly encourage researchers to adopt a CONSORT-like checklist that describes key design features for MBI. This checklist—and my adherence to it—is provided as a supplement in S Table 1.2.

1.5.4. Methodological rigour, hype, and publication bias

Many of the remaining criticisms of mindfulness-based intervention research extend to other interventions and psychology research, and these criticisms are indicative of wider concerns about the quality and replicability of psychological research (e.g., see: Ioannidis, 2005, 2012; Open Science Collaboration, 2012). Early criticisms of mindfulness meditation research include the lack of active comparison groups, short follow-up times, threats to validity (e.g., no accounting for social desirability), small and underpowered samples, a lack of evaluation of treatment fidelity or instructor training, and inappropriate statistical methods (e.g., see: Baer, 2003; Bishop, 2002). To these criticisms I would add: the conflation of statistical significance with clinical significance; the inappropriate use of pilot studies to infer changes in mental health outcomes (which is contrary to recommendations for how pilot data should be used, e.g., Lancaster, Dodd, & Williamson, 2004; Lee, Whitehead, Jacques, & Julious, 2014); the lack of reporting of conflicts of interest (which recently was cited as a partial reason for the retraction of a popular meta-analysis of MBI-based systematic reviews and meta-analyses (see: The PLOS ONE Editors, 2019, on: Gotink et al., 2015); and the increasing evidence of 'hype' (as defined by Meichenbaum & Lilienfeld, 2018; for evidence, see Van Dam et al., 2018).

Given that over a decade has passed since these criticisms were first put forth, it would be reasonable to expect that researchers had rectified their ways; yet a recent systematic review revealed that many of the criticisms still hold (Goldberg et al., 2017). Goldberg et al. identified 142 RCTs using MBI in clinical populations, published between 2000 and 2016. The included studies were coded for the following study quality features: use of an active

control condition, (larger) sample size, length of follow-up assessment, treatment fidelity, reporting of instructor training, and use of intention-to-treat (ITT) analyses. Less than 20% of studies used an evidence-based comparison group, and only 40% of studies matched treatment time between the MBI and control groups. Studies included on average 84.5 participants (SD: 71.19) and just over 50% of studies incorporated a follow-up assessment. Overall Goldberg et al. found no strong or convincing evidence that MBI research had improved over the 16 years, but concluded that it was at least heading in the right direction rather than deteriorating.

In a final damning indictment, Coronado-Montoya et al. (2016) demonstrated the strong likelihood of publication and reporting biases in MBI. In their review they compared the rate of reporting of positive results in mindfulness-based therapy against what might be expected if mindfulness-based therapy was as effective as individual therapy for depression. Less than 20% of the 124 studies were preregistered. Almost 90% of the studies reported one or more positive outcomes in the abstract (87%) and concluded that mindfulness-based therapy was effective (88%). Sample sizes ranged from 10 to 357 participants, but the average number of patients per trial was 70.3 (the median was 54.5). The rate of positive reporting was 1.6 times greater than would be expected if mindfulness-based therapy was as effective as individual therapy, and the rate of positive reporting was considerably higher when statistical power was low. None of the 36 systematic reviews and meta-analyses that were included reported that effect size estimates may be inflated due to reporting biases.

1.6. State of the evidence

The majority of meta-analyses included in this review reported that mindfulness-based interventions were either effective or partially effective, in producing improvements in the main psychological outcome variables. Importantly, however, the magnitude of effectiveness was not strong. That is, the majority of studies reported effect sizes in the range of .20–.50 (see Table 1.2.). Most meta-analyses included here focused on mental ill-being outcomes, e.g., psychological distress, depression or depressive symptoms, anxiety, and stress; fewer focused on mental well-being outcomes, e.g., resilience or flourishing, but most did include

mindfulness as an outcome (despite the problems with measurement outlined earlier). On the basis of the accumulated evidence discussed here, it seems that mindfulness interventions are associated with small to moderate effects on depressive symptoms, anxiety, stress, and some well-being measures in clinical populations and to a lesser degree in non-clinical populations including in university students.

It is, perhaps, unsurprising that effects are stronger in clinical populations, as these individuals generally have more room for improvement. Put another way, by virtue of *not being* depressed or anxious, healthy participants have scores on measures of depression or anxiety that do not allow for much improvement and thus demonstrate ceiling effects in mental health outcomes. Despite this, non-clinical populations still appear to benefit from MBIs.

The evidence is also stronger for specific MBIs. For instance, there is convergent evidence that MBCT is effective at reducing depressive relapse (see: Hofmann, Sawyer, Witt, & Oh, 2010; Kuyken et al., 2008; Piet & Hougaard, 2011). Given the supporting evidence for MBCT in clinically distressed populations, dissemination and implementation studies are required to establish effectiveness and to identify implementation strategies required in true clinical settings. Some of this work has begun, at least in terms of effectiveness (e.g., Tickell et al., 2019). Work on digital MBCT has also begun (e.g., Dimidjian et al., 2014) which may increase access to those who need it – although this research is in its infancy and more work is needed.

There is weaker evidence that mindfulness-based interventions can successfully be implemented as brief, online, or app-based interventions. But brief, online, and app-based interventions offer promising opportunities to overcome barriers to intervention, and two mindfulness meditation apps were the most popular apps in the 'self-care' category (Quinn, 2018), suggesting they are not going away. Nevertheless, further research is required to confirm their effectiveness and safety.

When comparing MBIs to no-treatment or waitlist, in general, the effects of mindfulness appear promising. Even when MBIs are compared to nonspecific active controls

(e.g., attention controls) there appears to be some unique benefit attributable to mindfulness practice. But when MBIs are compared to specific active control conditions such as CBT, there is little to no evidence that MBIs are superior to established treatments. Although some sceptics have interpreted a lack of superiority as sounding the death knell for mindfulness-based interventions (e.g., Coyne, 2016; Goroll, 2014), all this simply means is that MBIs are as effective as, or less effective than, some interventions, not that they are not effective at all. A practical implication for these findings is that a diverse array of psychotherapeutic options is necessary in clinical settings. To draw on an analogy used by Dunedin youth social worker, Hazel Cunliffe, when speaking to her clients, "learning skills to manage mood and anxiety is like being in a huge hat shop where you have to try lots of hats on; some will fit well and others you will put on and be uncomfortable with or they will just not feel quite right ... it's mostly letting them [your clients] know it's ok to explore and try new things but to expect some not to work for them" (personal communication, 2019). This analogy rings true for all psychotherapies: it is important to provide patients and clients with options so that if one therapy does not work for them there are others available for them to experiment with.

While the evidence for mindfulness-based interventions is growing, so too is the focus on methodological rigour (or lack thereof) in experimental research, and the critical evaluation of the accumulated evidence related to mindfulness meditation (e.g., Coronado-Montoya et al., 2016; Goldberg et al., 2017; Grossman & Van Dam, 2011; Van Dam et al., 2018). Even so, mindfulness interventions continue to be broadened in scope and have been integrated into settings outside of clinical treatment including in occupational settings (Bartlett et al., 2019), the military (Clark, 2018), corrections (Simpson, Mercer, Simpson, Lawrence, & Wyke, 2018), and with school-aged children and adolescents (Dunning et al., 2018; Zenner, Herrnleben-Kurz, & Walach, 2014). MBIs are also increasingly used in other health settings beyond the scope of this thesis including for pain (primarily oncological and chronic pain), substance use, and disordered eating. Although the evidence is promising, some researchers have suggested that the enthusiasm for mindfulness in these broader settings has moved ahead

of their evidential base (e.g., Farias & Wikholm, 2016; Greenberg & Harris, 2012), and that methodological rigour is required before we can support the use of MBIs outside of mental health (Shonin, Van Gordon, Slade, & Griffiths, 2013). Although I agree that interventions should not be disseminated until their effects are well understood, the popularity of mindfulness both in academic and mainstream media is increasing, as demonstrated in the Figure 1.1. reproduced from Van Dam et al. (2018) on page 1 of this thesis. Given the commercial growth described in the abridged timeline of this thesis (e.g., Schlagenhauf, 2018), criticisms and counter-criticisms of the widespread use of mindfulness are unlikely to slow the progression of its use. Therefore, I believe it is imperative to ramp up the scientific process to test the effectiveness of these *existing* and *widely used* mindfulness-based tools to begin to grow an evidence base, one way or the other.

Finally, while some have taken issue with the motivations of secular and clinical adaptations of mindfulness meditation—"it might just become another technique, stripped of all the very depth and wisdom that … carries the healing power inherent in mindfulness" (Williams & Kabat-Zinn, 2011, p. 9 in an editorial paraphrasing Maex, 2011)— as well as the lack of explicit ethical underpinnings (R. Baer, 2015; Monteiro et al., 2015), and the ongoing considerations into methodological rigour (or lack thereof), others have suggested that contemporary clinical applications of mindfulness have simply continued the Buddha's tradition of speaking the language of the listener (Maex, 2011). More specifically, they note that Buddhism was not intended to be dogmatic. In the oldest texts, the Buddha is reported to have restated his message in many different ways to suit the listener and student. This tradition has continued with the teachers of different schools of Buddhism, as described by Maex, "Chinese Buddhism is explained in a very Chinese way and Tibetan Buddhism in a Tibetan style" (Maex, 2011, p.167) and it continues with secular and clinical teachings of mindfulness in applications such as MBSR and MBCT (Maex, 2011). Further, some have suggested that the strand of meditation is less important than the sincerity of the practice (Batchelor, 2011;

Van Gordon et al., 2015). To this end, although Bodhi notes that secular and clinical applications of mindfulness are at odds with some of the Pāli canon, he also says:

> *I do not think we need to be alarmed about the adaptation of Buddhist practices for secular ends … If such practices benefit those who do not accept the full framework of Buddhist teaching, I see no reason to grudge them the right to take what they need. To the contrary, I feel that those who adapt the Dhamma to these new purposes are to be admired for their pioneering courage and insight. As long as they act with prudence and a compassionate intent, let them make use of the Dhamma in any way they can to help others.*
>
> Bodhi, 2011, p.36

CHAPTER 2: THE PRESENT THESIS

Mobile mindfulness meditation: A randomised controlled trial of the effect of two popular apps on changes in mental health[20]

This thesis consists of three empirical studies – one randomised, controlled-trial (RCT), and two targeted and pragmatic RCTs.

Study 1 was a 40-day randomised controlled trial (RCT) exploring the effect of mobile mindfulness app use on mental health in a convenience sample of young adults. Participants were randomly assigned to use one of two mindfulness meditation apps (Headspace or Smiling Mind) or an attention placebo control app (Evernote) over two brief periods: 1) a 10-day period where app adherence was requested and 2) a 30-day period where app use was at the discretion of the individual. Participants reported their mental health (depressive symptoms, anxiety, stress, flourishing, resilience, mindfulness, and adjustment to college) on Day 0 (baseline), Day 10, and Day 40. Adherence was self-reported (daily during the 10-day period, and using a single item question on Day 40 for the 30-day period).

Study 2 was a targeted, pragmatic, randomised, wait list, controlled trial with a complex research design whereby students presenting at the University of Otago's Student Health Services Counselling Service were given the option of trialling a mobile mindfulness meditation app at one of three time points in relation to their counselling treatment:

> *Pre-treatment:* Distressed students were provided with access to the tool in the interim between triage (presentation at the counselling service) and onset of treatment (typically 3–5 weeks) to use at their discretion.
> *Treatment onset:* Distressed students were provided with access to the tool to use at their discretion at the onset of treatment.
> *Treatment conclusion:* Distressed students were provided with access to the tool to use at their discretion at the end of treatment.

[20] This chapter is an adapted version of the manuscript: Flett, J. A. M., Hayne, H., Riordan, B. C., Thompson, L. M., & Conner, T. S. (2019). Mobile mindfulness meditation: a randomised controlled trial of the effect of two popular apps on mental health. *Mindfulness*, *10*(5), 863-876. doi: 10.1007/s12671-018-1050-9

Treatment plans differed for each patient who presented at the Counselling Service. Some patients received only one counselling session, whereas others received repeated sessions. The time between sessions was also patient-dependent. This created a complicated environment in which to conduct research. To overcome these obstacles I extensively consulted with clinicians to iteratively 'build' a research design that worked best with them while still providing clinically meaningful data. One such example is that 'stages' of the study were 'activated' by the clinician in an online portal. The online portal was used to automatically interact with participants. For example, the portal automatically sent an email with a survey to a participant when their clinician reported that the patient had concluded their treatment.

Despite extensive reductions in clinician burden I was unable to collect sufficient data to conduct the planned analyses regarding the effectiveness of mobile mindfulness in this population. This may have been due to the complex population (clinically distressed students), the complex problem (broadly defined clinical distress), the complex environment (a dynamic counselling service) in which this research was conducted, or a combination of these and other factors. Even so, I was able to capture a 'snapshot' of the population of distressed university students who were willing to trial mobile mindfulness meditation. With this in mind, I will outline the planned research protocol before summarising the recruitment data and characteristics of the distressed participants who registered willingness to trial an innovative intervention. I will then discuss the successes and failures in design, recruitment, and participant retention.

Study 3 was a targeted, pragmatic, randomised, wait list controlled trial that built on Study 1's findings. In this study I tracked the mental health, college adjustment, and academic achievement of a cohort of students living in one of two first-year residential colleges. At the beginning of the academic year, all residents of the two selected residential colleges were asked to complete an online survey about their mental health and university experiences. They were also asked whether they would like to trial an existing mobile mindfulness meditation

app, Headspace, for one semester. Those who opted in were randomly assigned to receive the app in either Semester 1 or Semester 2; those who opted out were asked to complete the surveys throughout the year. Participants were asked to complete an online survey of their mental health and adjustment to college life at three time points: the beginning of semester 1, the beginning of semester 2, and the end of the academic year. At the end of the academic year (with the permission of the participants), the University of Otago provided me with the participants' academic achievement data. Participants provided rich quantitative and qualitative (free-text) responses to open-ended questions.

2.1. Additional considerations for this thesis

2.1.1. Methodological perspective

Batchelor (2011) describes the Buddha as a pragmatist; in this thesis I have bypassed efficacy trials (Mohr, Lyon, Lattie, Reddy, & Schueller, 2017) and instead taken a pragmatic approach to effectiveness trials. Specifically, I have focused on establishing the degree of effectiveness of mobile mindfulness meditation apps when they are used by a diverse population in a naturalistic setting and where adherence is gently encouraged but not enforced (Mohr, Lyon, et al., 2017). To maximise the use of resources available for these studies, I have used three-arm designs where appropriate. Taken together, these methodological approaches balance thoroughness with expediency.

More specifically, I have prioritised a pragmatic approach to effectiveness trials in order to quickly generate evidence of effectiveness for mobile MBI in real-world settings. Pragmatic trials are those designed to "maximise applicability of the trial's results to usual care [real-world] settings" (CONSORT, 2008). Pragmatic trials are pertinent here because the rapid turnover in the mobile health and app industry means that by the time sufficient evidence is gathered using traditional research designs (Ioannidis, 1998), the technology is obsolete (Kumar et al., 2013). Recent figures suggest there are as many as 325,000 health apps available in app stores, with more than 200 new apps being added each day

(Research2Guidance, 2017). But, over 50% of health apps are downloaded fewer than 500 times (IMS, 2013). Further, traditional research designs overlook the complexities of human functioning and may only be considered valid under strict conditions, with in the settings in which the trials were originally conducted (Shean, 2015). If a mobile MBI is intended to be used in daily life, the most challenging test of its effectiveness will be to demonstrate its utility outside of those settings, most specifically settings wherein adherence to the intervention is not a given. Although I initially developed these methodological priorities independently, they have subsequently been better articulated as key components of the *Accelerated Creation-to-Sustainment Model* optimised for bridging the research-to-practice gap in digital mental health interventions (Mohr, Lyon, et al., 2017).

Finally, intervention research is resource intensive not only financially but temporally. For this reason I have tried to maximise the conclusions that can be made from each research trial by adopting a three-arm design where possible. In Study 1 this allowed me to explore *two* mMBI; in Study 2 this would have allowed me to make comparisons of mobile mindfulness alone and as compared to treatment-as-usual across several time points during the counselling treatment; in Study 3 I was able to track a self-selected non-random control to explore whether those who are more likely to opt-in to app-based mindfulness study differ from those who wouldn't. Adopting three-arm trials has maximised the conclusions I was able to make about mMBI in each trial but has also had implications for the statistical power and recruitment aims in these trials.

2.1.2. Statistical perspective

A mistake in the operating room can threaten the life of one patient; a mistake in statistical analysis or interpretation can lead to hundreds of early deaths. So it is perhaps odd that, while we allow a doctor to conduct surgery only after years of training, we give SPSS® (SPSS, Chicago, IL) to almost anyone.

Vickers (2005), p. 405

In line with my methodological pragmatism, in this thesis I take a straightforward, pragmatic, and consistent approach to statistical analyses. That is, I move from least complex to most complex statistical analyses, present results in ways that could be easily adapted to provide clinically meaningful take-home messages to practitioners and the public, and follow a repeated analytical approach across each randomised, controlled trial. Where there are deviations from the standard analytical protocol, I explicitly state whether the deviations were preregistered analyses or post-hoc exploratory analyses and provide justifications for these deviations (e.g., was the exploratory analysis in response to the data or was it in relation to an exploratory hypothesis). I do this in order to make all analytical decisions transparent.

Given the nature of this intervention, small effect sizes were expected because the interventions are brief, relatively self-directed, and often employ normative populations who do not have as much room to improve as clinical populations. Fortunately, small effect sizes can still be clinically meaningful if they are cost-effective, time-efficient, and relevant to the population's baseline (i.e., you should expect higher effect sizes in clinical populations; see Hays & Wooley, 2000, for further perspective on meaningful small effect sizes). As such, where appropriate, I have presented the effect size, 95% confidence intervals, and average percentage change in our tables. I believe this is an appropriate way of presenting these findings because these details allow the reader to draw their own conclusions on the basis of the data, and metrics such as percentage change easily convey meaning to lay audiences.

2.1.3. Technology of interest

You might be wondering why I chose to examine app-based mindfulness rather than web-based? Allow me to explain. The chances are, that as you read this thesis you have a mobile phone on your person or within one metre of your person. And, if you don't, the likelihood is that the next person you encounter does. Mobile phones are near ubiquitous, and the deep sense of reliance we as mobile phone owners have on them means they are kept near us at all times. Thus, mobile phones present an unparalleled point of access to individuals. We, as researchers, can rely on individuals to keep their device handy, and unlike earlier digital research (where researchers provided participants with PDA's), the individuals are also responsible for the maintenance of their mobile phones.

In the mindfulness sphere, digital apps represent the wild-wild west. Apps are being developed at an ever increasing rate (there are over 2000 mindfulness apps available in app stores), and they are being widely used (Schlagenhauf, 2018) despite little to no evidence of their effectiveness and safety on a global scale (mindfulness apps in general) or an individual scale (specific mindfulness apps). One of the main problems with mindfulness app companies, is that they claim to be evidence-based simply by virtue of delivering guided mindfulness content. They borrow from the, albeit exaggerated, efficacy of well-established (and more intensive) mindfulness programmes like MBSR and MBCT, to claim that their app is "supported by science" without actually testing the individual programme provided by the app.

Another challenge in testing mindfulness meditation apps is choosing the apps to test. Although a small number of mHealth apps are responsible for over 90% of consumer downloads (Aitken & Lyle, 2015), the majority of research-validated apps have already disappeared from the app stores (see Bakker et al., 2016 on Donker et al., 2013). For these reasons I agree with Meinlschmidt et al.'s (2016) assertion that there is little value in testing a single new app. Unlike Meinlschmidt et al. (2016), I instead believe there is value in identifying and testing popular and currently available apps that have a committed user-base

and are likely to remain in use in the near future. For these reasons, and more, in this thesis I have prioritised testing widely.

2.1.4. Population of interest

In this thesis I focus on the implementation of mMBI in young adult university students in Aotearoa New Zealand[21]. I do so for several reasons. First, in Aotearoa New Zealand, rates of psychological distress are generally increasing among adults (6.6% in 2006/07 – 7.6% in 2016/2017 – 8.6% in 2017/18; Ministry of Health, 2018; 24% of adults with medium or high distress: Kvalsvig & Health Promotion Agency, 2018) but are highest among young adults (36% medium or high distress 15–24 year olds (Kvalsvig & Health Promotion Agency, 2018; Ministry of Health, New Zealand, 2018). Second, the typical onset of many mental health disorders is in late adolescence and young adulthood (Newman, Moffitt, Caspi, Magdol, Silva, & Stanton, 1996). Third, evidence from Australia suggests that university students are an at-risk population with significantly higher psychological distress than the general population (Stallman, 2010). Further, almost one-third of all first-year university students surveyed as part of the WHO international college world mental health survey reported a history of at least one common DSM-IV mood, anxiety, or substance disorder (n = ~14,000 across eight countries not including New Zealand; Auerbach et al 2018). Fourth, young adults have lower rates of treatment or help-seeking (approximately one in four with diagnoses seek help in NZ sample; Newman et al., 1996) despite reporting barriers to treatment and help-seeking that are similar to older adults (e.g., cost, geographic distance, and stigma; Collins, Westra, Dozios, & Burns, 2014; Rickwood, Deane, & Wilson, 2007). But young adults also turn to the internet as their first stop for health information (Myrick, Willoughby, & Verghese, 2016). Fifth, 91% of 18–34-year-olds own a smartphone, the majority of adults use it daily (91%) and it is their preferred device (59%; Research New

[21] Although I am primarily interested in young adults I did not limit participation in my studies to this population. I deemed this to be acceptable because the average age (and +1SD) of participants in each study included in this thesis fall into the young adult age range (18–25 years old) and I did not find any evidence that the one or two adults aged 25+ in each study impacted the results.

Zealand, 2015). Recent reports suggest that the preference for digital psychotherapeutic interventions (as compared to face-to-face therapy) is increasing (Renn, Hoeft, Lee, Bauer, & Arean, 2019). In an Australian sample, younger age and higher education (as well as female gender, being married, and a positive attitude toward professional help-seeking) were factors that predicted higher preference for online mental health interventions and lower preference for face-to-face therapy (Batterham & Calear, 2017). And finally, university students represent a demographically diverse, but captive, adult audience; it is my opinion that there is unlikely to be a better time to intervene with such a diverse group of adults.

Mindfulness meditation may also be an appropriate choice for Māori young adult university students. Some academics have argued that elements of mindfulness overlap with Māori ways of seeing the world and that MBI may help bridge the gap between traditional Māori understandings of health and the existing medical models of health (Ketu-McKenzie, 2019). This is an especially important consideration given that mental distress is disproportionately higher in Māori than non-Māori (Russell, 2018).

2.1.5. Outcomes of interest[22]

The primary objective for any mental health intervention is to improve psychological symptoms, and thus changes in mental health outcomes are the primary interest of this thesis. But health is not simply the absence of disease or illness, and for this reason in this thesis 'mental health' describes both negative (e.g., depressive symptoms) and positive (e.g., resilience) psychological factors that contribute to an individual's overall mental state. This sentiment has been shared widely by organisations such as the World Health Organisation and the American Psychological Association and has also been reiterated in relation to the improvement of tertiary student health (Grace, 1997), but its origins can also been traced to

[22] Retrospectively, these outcomes of interest also fit the *Accelerated Creation-to-Sustainment Model*'s "objectives [outcomes] of optimization" (Mohr, Lyon, Lattie, Reddy, & Schueller, 2017, p.7). That is, our primary objectives [outcomes] are improvements in psychological health; our technology objectives [outcomes] include markers of usability (participant rated usefulness, ease of use); and, our implementation objectives [outcomes] include uptake and rate of use.

Buddhism.[23] The psychometrically validated outcomes used in studies presented in this thesis are provided in Table 2.1.

I also have several secondary outcomes of interest including those associated with app quality such as technical quality and user experience. Although these factors are not directly implicated in the effectiveness of the *therapy* delivered by the apps, they likely have a large impact on adherence to the intervention, which in turn is strongly tied to therapeutic effectiveness (DiMatteo, Giordani, Lepper, & Croghan, 2002). I am also interested in intervention non-specific outcomes such as therapeutic alliance (and therapist effects in Study 2) and expectations of (app-based) treatment. These intervention non-specific factors typically account for more of the variability in participant outcomes than the intervention (Cuijpers et al., 2012; Wampold et al., 1997).

In this thesis I have tried to maintain continuity of psychometric measures across the course of the studies in order to make deductions about populations across the studies, but this is not without its complications. In study 1, where I am trying to evaluate whether mindfulness programmes can provide any of the benefits claimed by other formal programmes, I favoured a 'more is more' approach to demonstrate the wider effects of the mobile MBIs. In later studies where I have targeted specific populations, I have favoured a more concise approach. As such, over the course of these studies I have refined the outcome measures to minimise participant burden in terms of both frequency and length of assessments.

[23] In the 1970s, psychologist, Erich Fromm (1900-1980) first proposed health from a well-being perspective, rather than simply the absence of illness. Specifically, Fromm thought that that meditation could be used to aid psychotherapy beyond symptom relief. Fromm was informed by his studies of Zen Buddhism and discussions with Zen scholar Daisetz T Suzuki (Fromm, Suzuki, & De Martino, 1993, p. 137)

Table 2.1.

Psychometrically validated outcome measures included in randomised, controlled trials in this thesis.

Measures	**Study 1**	**Study 2**	**Study 3**
Study description	3-arm RCT comparing Headspace, Smiling Mind, and a Control in student convenience population	3-arm RwCT comparing Headspace, Smiling at three time-points in relation to counselling in distressed students	RwCT comparing access to Headspace in first semester vs. second semester in incoming students
Ill-being			
Psychological Distress (K10)		Primary	Primary
Depression			
CES-D	Primary		
BDI II		Secondary	
Anxiety			
HADS-A	Primary		
BAI		Secondary	
Stress	Primary		
Well-being			
Mindfulness	Secondary	Secondary	Secondary
Resilience	Secondary	Secondary	Secondary
Flourishing	Secondary	Secondary	
Other			
College Adjustment	Secondary		Secondary
Forgiveness	Exploratory		
Personality	Exploratory		
TIPI	Exploratory		
NEO-FFI			
Interpersonal Support	Exploratory		
Personal Growth	Exploratory		
Self-efficacy			Secondary
Affective Tendencies	Exploratory		
Academic achievement			Secondary
Supporting			
App use	Self-report	Objective	Objective
Expectations/Perceptions	Self-report	Self-report	Self-report

N.B. Primary = Primary outcome, Secondary = Secondary outcome, Exploratory = Exploratory outcome.

All primary and second outcomes were pre-registered unless otherwise stated. For brevity, not all exploratory outcomes will be explored in this thesis and are simply included for transparency.

CESD = Center for Epidemiological Studies – Depression Scale (Radloff, 1977); BDI-II = Beck Depression Inventory II (Beck, Brown, Epstein, & Steer, 1988); HADS-A = Hospital Anxiety and Depression Scale – Anxiety subscale (Zigmond & Snaith, 1983); BAI = Beck Anxiety Inventory (Beck et al., 1988); TIPI = Ten Item Personality Inventory (Gosling, Rentfrow, & Swann, 2003); NEO-FFI = Neuroticism, Extraversion, Openness Five Factor Inventory (Costa Jr. & McCrae, 2008); Interpersonal support, Interpersonal Support Evaluation List (Cohen & Hoberman, 1983). Personal Growth, Personal Growth Inventory (Robitschek, 1998). Self efficacy (Chen, Gully, & Eden, 2001). Affective Tendencies, Circumplex Model of Affect (Barrett & Russell, 1999).

2.1. Overall Aims

Collectively the aims of the current thesis were:

1. To explore how mobile mindfulness meditation broadly impacts mental health when delivered in naturalistic settings.
2. To explore whether mobile mindfulness meditation that is targeted at specific populations is associated with mental health improvements, when delivered in naturalistic settings.
3. To explore whether there is a 'dose-response relationship' between mobile mindfulness meditation use and changes in mental health.

CHAPTER 3: STUDY 1

Mobile mindfulness meditation: A randomised controlled trial of the effect of two popular apps on changes in mental health[24]

3.1. Overview and Rationale

As established in the literature review, mobile mindfulness-based interventions present a promising opportunity to overcome challenges associated with traditional face-to-face mindfulness instruction. They are also prevalent in app stores. Despite this potential, at the outset of this thesis, few studies had rigorously examined the effectiveness of mobile mindfulness apps for improving mental health in normative or clinical populations (Mani et al., 2015; Plaza et al., 2013). The paucity of research on mobile mindfulness apps at the beginning of my PhD was compounded by the high turnover rate for mindfulness meditation apps in app stores (Bakker et al., 2016; Donker et al., 2013; Larsen et al., 2016), and the relatively slow pace at which research proceeds to publication (approximately 5.5 years from start of enrolment to publication; Ioannidis, 1998). In this chapter, I present one of the first randomised, controlled trials on the effectiveness of two mobile MBIs on changes in mental health compared to an attention placebo control app. This study represents an essential first step in this area of research and provides justification for the remaining two experimental studies in Chapters 4 and 5. Thus, in this chapter I determine the effects of mobile mindfulness on mental health and identify where mobile mindfulness might make the most impact.

Here, I present a pre-registered randomised, controlled trial of the effectiveness of two popular and currently available mindfulness meditation apps – Headspace and Smiling Mind – on changes in mental health compared to an attention placebo control app. I selected Headspace and Smiling Mind based on several factors: both apps have a high download rate (over 100,000 downloads at the time of data collection, suggesting a higher user-base), both

[24] This chapter is an adapted version of the manuscript: Flett, J. A. M., Hayne, H., Riordan, B. C., Thompson, L. M., & Conner, T. S. (2019). Mobile mindfulness meditation: a randomised controlled trial of the effect of two popular apps on mental health. *Mindfulness*, *10*(5), 863-876. doi: 10.1007/s12671-018-1050-9

have similar introductory mindfulness meditation practices that have been well-received by users (e.g., Headspace: 4.7 stars v. Smiling Mind 3.7 stars in Google Play Store at the time of writing the peer reviewed manuscript), and both have high-quality ratings as assessed by the Mobile Application Rating Scale (MARS; (Stoyanov et al., 2015); 4.0 and 3.7 out of 5.0, respectively; median MARS score of 23 apps was 3.2 out of 5.0; (Mani et al., 2015). A key difference is cost; Headspace incurs a fee after a brief trial, whereas Smiling Mind is free. While neither app is necessarily comparable with more rigorous and evidence-based multi-week programmes like MBSR (Kabat-Zinn, 1982), they do provide a number of meditations consistent with common meditation practices (Kabat-Zinn, 2013) which may make them acceptable introductory mindfulness tools. As in prior work (Howells et al., 2016), I also incorporated an app-based attention placebo control condition (Evernote) to help account for digital placebo and treatment expectancies (Torous & Firth, 2016). I examined changes in mental health outcomes over a short-term adherence-requested period (10 days) and over a medium-term discretionary-use period (30 days) to mimic both optimal and naturalistic use and uptake of the app.

3.1.1. Research questions and hypotheses

In consultation with the literature available at the time (c2015), I identified the following research questions and defined the following hypotheses:

1. How is participation in a mobile mindfulness programme associated with changes in mental health in an adult student population?

   H1: Individuals using the mindfulness apps would report improved mental health outcomes from baseline to the 10-day follow up, compared to those using the attention control app.

2. Does app use change over the course of study participation?

   H2: App usage would be higher during the initial 10-days of access where adherence was requested, and much lower during the subsequent 30-days of access where adherence was at the discretion of the individual. This prediction is based on evidence that health and fitness app usage typically drops off to below 50% user retention after one month (Farago, 2012).

3. Are improvements contingent on frequency of app use? That is, is there a 'dose-response' relation between mobile mindfulness app use and changes in mental health?

   H3: In line with prior work (Bostock, Crosswell, Prather, & Steptoe, 2019) (Bostock & Steptoe, 2013), I predicted that sustained improvement in mental health outcomes for mindfulness app users (but not attention control app users) following the 30-days of discretionary use would only occur for those who continued to use the app.

3.2. Method

3.2.1. Design

The study consisted of a pre-registered three-arm randomised controlled trial (RCT) that tested the effect of two mobile mindfulness apps (Headspace and Smiling Mind) on changes in mental health, relative to an attention control app (Evernote). The trial and outcome measures were registered prior to recruitment with the Australia and New Zealand Clinical Trials Registry (#368325). The pre-registered mental health outcome measures were depressive symptoms, anxiety, and stress as primary outcome measures, and mindfulness, resilience, flourishing, and college adjustment as secondary outcome measures. The mental health measures were completed at three time points: at baseline before the intervention (Time 0), following a 10-day trial of their randomly assigned app (Time 1), and following a further 30-day access to their assigned app to use at their own discretion (Time 2). At an alpha level of .05, power of .80, and expected effect sizes of between d = .36 (informed by the depressive symptoms effect size I calculated for Howell et al., 2016 – an app-based mindfulness intervention) and d = .62 (informed by the .41 and .62 effect sizes for depression/anxiety and stress, respectively, in Cavanagh et al., 2013 – an online mindfulness-based intervention), I registered a recruitment target of 80 participants per condition (i.e., between 42 [d = .62] and 125 [d = .356] participants per condition). I fell short of this recruitment number by approximately 10 people per condition.

3.1.2. Participants

Participants were a convenience sample of 208 undergraduate students between 18 and 49 years old (*M* = 20.08 years, *SD* = 2.8 years) from the University of Otago. An additional two participants did not complete the required study measures and thus were excluded from analysis (see CONSORT diagram in Figure 3.1. for further details). Participants were largely of New Zealand European/Pākehā descent (73.6%; 12.0% Asian; 5.8% Māori or Pacific Islander; 8.6% other) which reflected demographics of the wider university community. Participants were recruited from April–August 2015 through the Department of Psychology's online psychology research participation pool where research participation served as an educational experience and could be applied to a small component of participants' undergraduate Psychology course grade based on completing a worksheet. Informed consent was obtained from all individual participants included in the study. I recommended that participants access the university's primary healthcare provider if they had any concerns about their feelings before, during, or after the study. This study was approved by the University of Otago Psychology Department, with oversight and approval by the University of Otago Human Ethics Committee (D15/063).

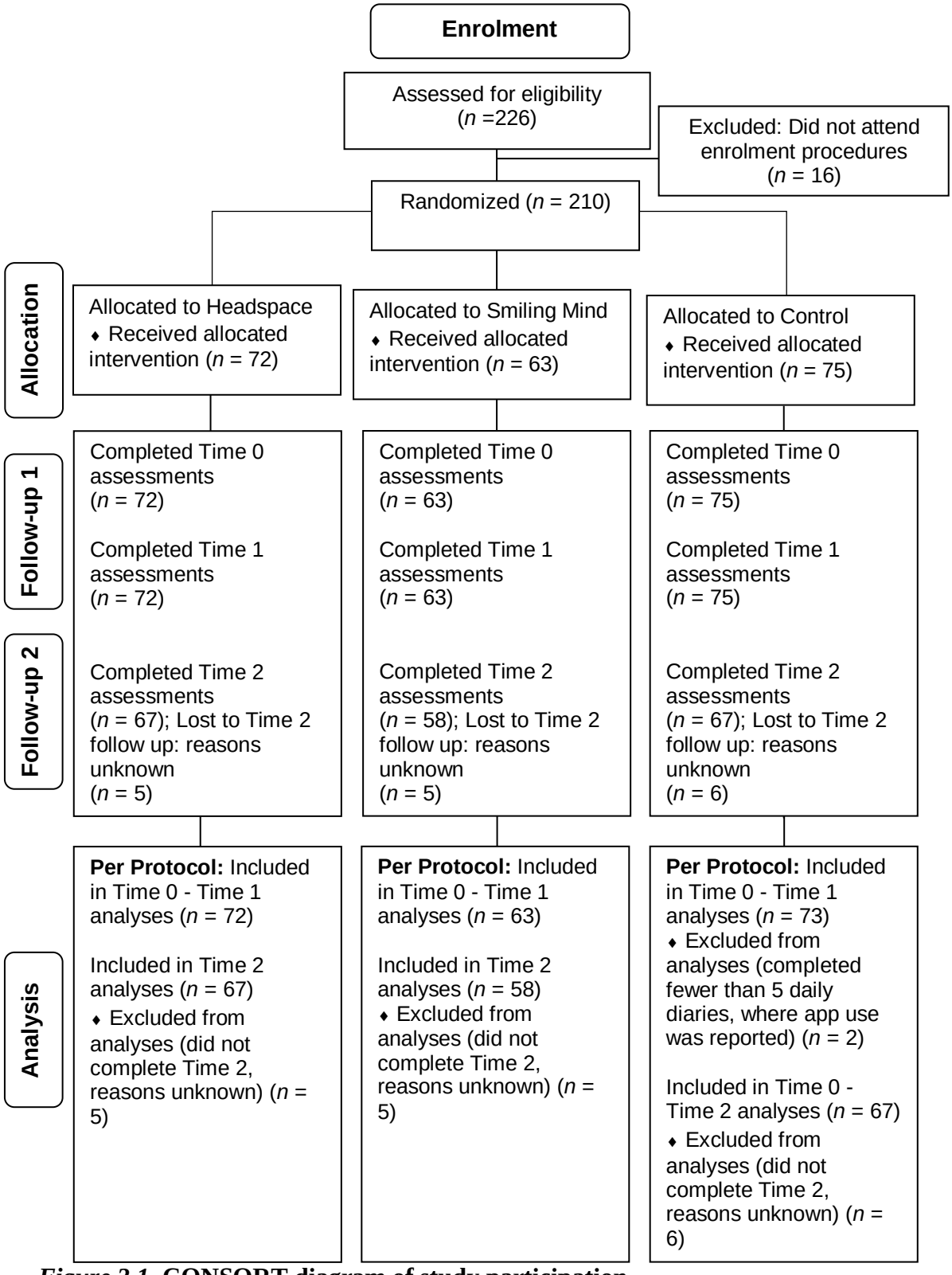

Figure 3.1. **CONSORT diagram of study participation.**

3.1.3. Applications

Headspace

Headspace is a smartphone application that offers hundreds of hours of guided and unguided mindfulness meditations delivered by Andy Puddicombe (a novice monk in the Theravada Tradition and a fully ordained Tibetan Buddhist monk in the Karma Kagyu Lineage; (Puddicombe, n.d.). At the time of this research, the app was structured so that participants were required to complete the Foundation Level 1 training (previously known as 'Take 10'; available free of charge) before accessing other content in the app (available following purchase). Foundation Level 1 is a 10-day introduction to mindfulness with 10-minute long formal meditation practices such as mindful breathing (i.e., using the breath as an attentional object of intense focus), body scan (systematically focusing on certain parts of the body), sitting meditation, practice of non-judgment of thoughts and emotions, and other guided meditations that vary the orientation (inward vs. outward vs. no orientation), spatial focus (fixed vs. moving), and aperture of attention (narrow vs. diffuse). Headspace is currently available on iOS and Android platforms and is also accessible via the Headspace website. Participants randomised to the Headspace condition were instructed to download the app and complete the Foundation Level 1 training across 10 days. Following the introductory period, participants were invited to access the other meditation tracks for the next 30 days using a pre-paid Headspace voucher to access the paid content.

Smiling Mind

Smiling Mind is a not-for-profit smartphone application developed by psychologists and educators that offers hundreds of hours of guided and unguided mindfulness meditation practices across several different mindfulness programmes targeting different age groups (e.g., 16–18 years, adults) and themes (e.g., mindfulness in the classroom, workplace, or to complement sports training). The meditations vary in duration from one minute to 45 minutes. Smiling Mind is available free of charge. It is currently available on iOS and Android platforms and through the

Smiling Mind website. Participants randomised to the Smiling Mind condition were instructed to download the app and use the 'For adults' programme for 10 minutes each day for 10 days. The 'For adults' programme features practices such as mindful breathing, body scan, mindful eating (i.e., focusing intently on the thoughts, feelings, and experiences of eating a piece of food), sitting meditation, practice of non-judgment of thoughts and emotions, and other guided meditations that vary the orientation (inward vs. outward vs. no orientation), spatial focus (fixed vs. moving), and aperture of attention (narrow vs. diffuse). If participants ran out of content on that programme during the 10 days, they were instructed to revisit the content they enjoyed or to try out a different programme. Following the 10 days, participants were invited to continue using Smiling Mind for the next 30 days.

Evernote (attention control application)

Evernote is an organisation application with a variety of free and pay-for features. Participants randomised to the control condition were instructed to download the Evernote app and use the note-taking function to "jot down all the things you can remember doing on this day last week" for 10 minutes every day, following a similar control procedure as used in (Howells et al., 2016) and (Lyubomirsky, Dickerhoof, Boehm, & Sheldon, 2011). Unlike previous research, I provided a more elaborate cover story by describing this activity as a means to practice 'organisational reminiscing' (See Supplement 3.1. for precise scripts). In doing so, I aimed to account for placebo and digital placebo effects (Torous & Firth, 2016). As with the other conditions, following the initial 10-day period, participants were invited to continue using Evernote for the next 30 days.

3.1.4. Measures

Demographic and covariate measures

The initial laboratory session included a survey containing a number of demographic measures including age, gender (male, female), and ethnicity using Aotearoa New Zealand 2013 census categories (Māori, NZ European/Pākehā, Pacific Islander, Asian, Indian, Middle

Eastern/Latin American/African, other European, other [please describe]). If 'other' was chosen, participants were able to elaborate using a free-text entry.

Depressive symptoms

Symptoms of depression were assessed using the 20-item Center for Epidemiological Studies Depression Scale (CES-D; (Radloff, 1977). Participants rated how much they had experienced a range of depressive symptoms over the past week (e.g., I was bothered by things that don't usually bother me) on a four-point scale ranging from 0 [Rarely or none of the time (< 1 day)] to 3 [Most or all of the time (5–7 days)]. Items were summed to create a score ranging from 0–60, with higher scores indicating more symptoms of depression. Although I analysed the CES-D as a continuous measure, a score of 16 or higher is frequently used to identify individuals experiencing significant symptoms of depression (Lewinsohn, Seeley, Roberts, & Allen, 1997). This scale has high internal consistency (αs .89, .91, and .93 at Time 0, Time 1, and Time 2 survey points in this study respectively, similar to α .85 in (Radloff, 1977) and acceptable concurrent and discriminant validity (Radloff, 1977).

Anxiety

Anxiety was assessed using the Hospital Anxiety and Depression Scale – Anxiety Subscale (HADS-A; (Zigmond & Snaith, 1983). Participants rated how much they agreed with seven statements (e.g., I feel tense or 'wound up') over the past week using a Likert scale from 0 [e.g., Not at all] to 3 [e.g., Most of the time]. Responses were summed over the seven items to obtain a score for each participant ranging from 0–21, with higher scores indicating greater anxiety. This scale has high internal consistency (αs .81, .81, .83 at Time 0, Time 1, Time 2, respectively) and *good* to *very good* concurrent validity (Bjelland, Dahl, Haug, & Neckelmann, 2002).

Stress

Perceived stress was assessed using the 10-item Perceived Stress Scale (PSS; (Cohen, 1988). Participants rated how often they experienced 10 statements over the past month (e.g., In the last month, how often have you felt confident about your ability to handle your personal problems?) using a Likert scale from 0 [Never] to 4 [Very often]. Responses were summed over

the 10 items to obtain a score for each participant ranging from 0–40, with higher scores indicating greater perceived stress. This scale has high internal consistency (αs .87, .89, .90 at Time 0, Time 1, Time 2, respectively) and acceptable convergent and divergent validity (Roberti, Harrington, & Storch, 2006).

Resilience

Resilience was assessed using the six-item Brief Resilience Scale (B. W. Smith et al., 2008), a measure of the ability to bounce back or recover from stress. Participants rated how much they generally agreed with six statements (e.g., I tend to bounce back quickly after hard times) using a Likert scale from 1 [Strongly disagree] to 5 [Strongly agree]. Responses were averaged across the six items to obtain a score for each participant ranging from 1–5, with higher scores indicating greater resilience. This scale has high internal consistency (αs .88, .87, .89 at Time 0, Time 1, Time 2, respectively, similar to αs .80 to .91 in (Smith et al., 2008), good test-retest reliability and acceptably convergent and divergent validity (Smith et al., 2008).

Flourishing

Flourishing was assessed using the eight-item Flourishing Scale (Diener et al., 2010), a measure of perceived achievement in areas such as relationships, self-esteem, purpose, and optimism that is commonly used as a proxy for psychological well-being. Participants rated how much they agreed with eight statements in general (e.g., I lead a purposeful and meaningful life) using a Likert scale from 1 [Strongly disagree] to 7 [Strongly agree]. Responses were summed over the eight items to obtain a score for each participant ranging from 8–56, with higher scores indicating greater well-being. This scale has high internal consistency (αs .88, .94, .95 at Time 0, Time 1, Time 2, respectively, similar to α .87 in (Diener et al., 2010), and .91 and .81 in (Hone, Jarden, & Schofield, 2014), good test-retest reliability (Diener et al., 2010) and adequate convergent and divergent validity (Hone et al., 2014).

College adjustment

College adjustment was assessed using the 19-item College Adjustment Test (Pennebaker, Colder, & Sharp, 1990), which captures experiences related to adjusting to college life in terms of positive affect, negative affect, and homesickness. Participants rated to what

extent they had experienced 19 statements in the past week (e.g., worried about how you will perform academically at college) on a scale of 1 [Not at all] to 7 [A great deal]. Items were reverse scored where appropriate and summed to create a score from 19–133, with higher values indicating greater adjustment to college. This scale has high internal consistency (αs .83, .85, .86 at Time 0, Time 1, Time 2, respectively, similar to α .79 in (Pennebaker et al., 1990) and good test-retest reliability (Pennebaker et al., 1990).

Mindfulness

Mindfulness was assessed using the 12-item Cognitive Affective Mindfulness Scale – Revised (Feldman, Hayes, Kumar, Greeson, & Laurenceau, 2006), a scale consisting of several facets of mindfulness including attention, present focus, awareness, and acceptance. Participants rated how much each statement applied to them in general (e.g., it is easy for me to concentrate on what I am doing) using a Likert scale from 1 [Rarely/Not at all] to 4 [Almost always]. Responses were summed over the 12 items to obtain a score for each participant ranging from 12–48, with higher scores indicating a greater level of the mindfulness facets: attention, present focus, awareness, and acceptance. This scale has acceptable internal consistency (αs.78, .84, .86 at Time 0, Time 1, Time 2, respectively, similar to αs .74 and .77 in (Feldman et al., 2006) and acceptable convergent and discriminant validity (Feldman et al., 2006).

Expectation and perceptions of app use

Participants were asked to rate their randomly assigned practice of either mindfulness meditation (Headspace, Smiling Mind) or organisational reminiscing (Control; Evernote) through two questions ('How useful do you think mindfulness meditation / organisational reminiscing would be for yourself [Time 0]/has been for yourself [Time 1, Time 2]?' and 'How effective do you think mindfulness / organisational reminiscing would be for yourself [Time 0]/ has been for yourself [Time 1, Time 2]?') on a scale from 1 [Not at all] to 4 [Very useful]. Scores on these two items were highly correlated (*r*s > .76) and averaged at each time point. Higher scores indicated a higher overall positive expectation (at Time 0) or perception (at Time 1 and Time 2) of utility and effectiveness their assigned activity.

App adherence[25]

App adherence during the first 10 days was assessed via an online daily diary sent directly as a hyperlink to participants' mobile phones at 7 pm every day for 10 days. Participants were asked if they had completed a session using their app today (yes/no), and yesterday (yes/no) to capture app use after the previous day's survey and/or account for missing surveys. These questions were embedded in a number of daily measures outside of the scope of this thesis. Daily diaries were lagged to account for missing diaries to create an overall measure of activity adherence as a sum from 0 (app used on zero days) to 10 (app used on all 10 days). App adherence for the 30-day open access to the app was assessed using a single question in the final survey asking "How often did you use the app in the last 30 days?" with answer options including 0 [Never], 1[Once], 2 [2–4 times a month], 3 [2–3 times a week], 4 [4 or more times a week], 5 [Daily or almost daily].

Personality and Individual Differences

Personality was measured at Time 0 using the Ten Item Personality Inventory (Gosling et al., 2003) in which the personality traits (agreeableness, conscientiousness, emotional stability, extraversion, and openness to experiences) were measured using a mean of two items. Participants rated agreement on a seven-point Likert scale (1: strongly disagree-7: strongly agree). αs were 0.40, 0.50, 0.73, 0.68 and 0.45 for the agreeableness, conscientiousness, emotional stability, extraversion, and openness to experience personality traits.

Tendency to pursue personal growth was measured using the Personal Growth Initiative Scale (PGIS, Robitschek, 1998), a measure of a "person's active and intentional involvement in changing and developing as a person". Participants rated how much they agreed with nine statements in general (e.g., I know how to change specific things that I want to change in my life) using a Likert scale from 1 [Definitely disagree] to 6 [Definitely agree]). Responses were summed over the nine items to obtain a score for each participant ranging from 9–54, with higher scores

[25] In advance of this trial, I informed the proprietary owners of the mobile mindfulness apps of my intention to complete this study and invited them to provide *objective* adherence data. Both parties declined and thus I have relied upon self-reported app use in Study 1. Headspace agreed to provide objective use data in subsequent studies. Smiling Mind did not respond to further requests.

reflecting higher intentions to pursue personal growth. αs. were .88, .90, .93 at Time 0, Time 1, Time 2, respectively.

These measures were included to investigate whether personality and tendency to pursue personal growth are related to self-reported adherence.

3.1.5. Procedure

Participants met with a researcher in groups of one to five people in a psychology laboratory to complete study enrolment. There were up to three study enrolment sessions per day. Using a random number generator, each enrolment session was randomly assigned to an app condition meaning that all participants in a shared session were assigned to the same condition. Following online informed consent, participants completed a survey of basic demographic information (age, gender, and ethnicity), the Time 0 mental health measures (depressive symptoms, anxiety, stress, resilience, flourishing, college adjustment, and mindfulness), and perceptions of their assigned practice (mindfulness meditation or control task) on computers in private cubicles. Next, they received instructions for their randomly assigned condition and were asked to download the app prior to leaving the lab. Starting that day, participants completed a 10-day trial of their randomly assigned app (Headspace n = 72; Smiling Mind n = 63, or attention control app n = 73). Participants were encouraged to complete one 10-minute session on their app each day during the first 10 days.

Starting the first night of the 10-day trial, participants completed a short daily online survey (sent via SMS) of activity adherence. Following the 10-day trial, participants completed a follow-up survey that was sent to their email address (Time 1). Excluding demographic questions, this survey was identical to the one they completed at Time 0. Finally, all participants were given an additional 30-day access to their assigned app to use at their own discretion. For Headspace users, this involved emailing them a ‘user code’ voucher which they could apply online to gain an addition 30-days of access to the content; for Smiling Mind and attention control app users, this involved emailing them to inform them that their access had rolled over. All participants were told to use the apps at their own discretion and that their app use would not be actively tracked.

Participants completed a final survey (Time 2; identical to the Time 1 survey) at the end of their 30-day access. All participants were debriefed about the nature of the study via email approximately two weeks after the Time 2 survey. Participants could receive a small amount of course credit upon completion of a worksheet about the study, but no remuneration was tied to app adherence.

3.1.6. Data analyses

Prior to our main analyses, I conducted between-group comparisons of baseline characteristics (demographic and Time 0 mental health measures) to test for equivalency of conditions at trial outset. I also computed changes in mental health within each condition separately in order to show the effect sizes (within Cohen's *d*; between Hedges' *g* with correction factor) prior to conducting our main analyses. This was done using paired t-tests to measure changes in mental health from Time 0 to Time 1 (baseline to the end of the 10-day period) and, from Time 0 to Time 2 (from baseline to the end of the 30-day discretionary period, approximately 40 days after baseline) within each condition separately.

For our main analyses, I used a multiple regression approach to compare the changes in the mental health outcomes over time between the three conditions using dummy codes. A regression approach was used instead of ANOVA because it provided more flexibility, precision, and consistency in analysing group differences and patterns of moderation by app use. The first set of regressions compared changes in mental health from Time 0 to Time 1 (baseline to the end of the 10-day period) between the three conditions. The outcome measure was mental health after the 10 days of app use (e.g., depressive symptoms at Time 1), which was predicted from mental health at baseline (e.g., depressive symptoms at Time 0), plus two condition dummy codes with the control condition as the reference group [Dummy 1= Control (0), Headspace (1), Smiling Mind (0); Dummy 2= Control (0), Headspace (0), Smiling Mind (1)].

I conducted these analyses a second time using Headspace as the reference group in order to establish whether there were any differences between the two mindfulness apps [Dummy Code

2 = 0 (Control), 0 (Headspace), 1 (Smiling Mind); Dummy Code 3 = 1 (Control), 0 (Headspace), 0 (Smiling Mind)]. The second set of regressions compared changes in mental health from Time 0 to Time 2 (baseline to the 30-day follow up) between the three conditions following a similar process as with testing from Time 0 to Time 1. For analyses of the Time 2 mental health measures, the sample size was reduced from 208 to 192 because 16 participants did not complete the Time 2 survey (7.7% attrition; see CONSORT diagram in Figure 3.1. for details).

The third set of regressions consisted of moderation analyses to determine whether frequency of app use during the 10-day and 30-day discretionary period moderated the effect of condition on changes in mental health from Time 0 to Time 1, and from Time 0 to Time 2, respectively. This was done by adding self-reported app use (10-day or 30-day) (centered), plus the cross-product interaction terms between app use (centered) and the group dummy codes (e.g., app use centered x Dummy Code 1 and app use centered x Dummy Code 2; then, separately, app use centered x Dummy Code 2 and app use centered x Dummy Code 3) to the regression models. Lastly, in all models, I had originally controlled for participants' age, gender, ethnicity, and previous experience with mindfulness/organisational reminiscing, but removed them from the final models because they did not affect the results. However, the final models controlled for app expectation scores (average of expected usefulness and effectiveness at Time 0, mean centered, in Time 0 to Time 1 analyses) or app perception scores (average of perceived usefulness and effectiveness at Time 1, mean centered, in Time 0 to Time 2 analyses).

Finally, I conducted post-hoc exploratory analyses. First, I conducted correlational analyses to determine whether any demographic, personality, or baseline mental health characteristics predicted self-reported app use (A: during the 10-day trial where adherence was requested and B: during the 30-day period where use was at the discretion of the participant). Second, I conducted exploratory analyses on the tendency to want to change or grow. On the basis of these post-hoc exploratory analyses I identified that there was a justification for controlling for the tendency to want to change or grow in the regression analyses.

3.3. Results

The results are reported in four sections. In the first section, I report descriptive statistics for the demographic information and baseline mental health measures, and the frequency and expectations of app use (H2). In the second section, I report the changes in mental health over time (within condition) and by condition (between condition) for the primary and secondary outcomes (H1). In the third section, I report the app use frequency as a predictor of mental health (H3). In the fourth section, I report post-hoc and exploratory analyses.

3.3.1. Descriptive statistics, baseline characteristics, and app use

Table 3.1. presents the demographic characteristics and baseline mental health measures for the sample overall and separately for the three conditions. Chi-square tests and one-way ANOVAs showed no significant differences between conditions in any of the preregistered baseline measures (all *p*s >.25). There was, however, a baseline difference in an exploratory measure—personal growth, the tendency to want to change or grow (PGIS, Robitschek, 1998)—between conditions ($F(2,205) = 39.02$, $p < .001$). Where cut-offs exist, participants' average scores fell into the commonly accepted normative ranges [depressive symptoms (Radloff, 1977); anxiety (Snaith, 2003); resilience (Smith, Epstein, Ortiz, Christopher, & Tooley, 2013)], although, notably a substantial minority of participants scored above the commonly accepted cut-off for significant symptoms of depression (CESD = 16+, 38.5%, $n = 80$).

At baseline, a subset of participants from each condition (control: 31.5%, Headspace: 25.0%, Smiling Mind: 27.0%) reported that they had previous experience with their assigned activity (mindfulness meditation or the attention-placebo control activity, organisational reminiscing). There were no significant differences between conditions in reports of previous experience with mindfulness or organisational reminiscing nor perceived usefulness or effectiveness of the tool (all *p*s >.20), suggesting that the control task was a theoretically feasible attention-placebo. However, as shown in Table 3.2., there were differences at Time 1 and Time 2 for perceived usefulness and effectiveness whereby participants in the mindfulness app conditions

reported that the tool was more useful and effective than participants in the control condition (all *p*s < .05) suggesting that in practice, the mindfulness tasks were more convincing than the control task.

Participants reported high app adherence between Time 0 to Time 1, using their app on 8.24 days out of the maximum 10 for Headspace users (*SD* = 2.02, range 2–10), on 8.00 days for Smiling Mind users (*SD* = 2.03, range 3–10) and on 8.74 days for attention control app users (*SD* = 1.76, range 2–10), which did not differ between conditions ($F(2,205) = 2.63$, $p = .075$). Consistent with H2, app use during the 30-day open access period was much lower. Nearly half of all participants reported 'never' using their app again during that 30-day discretionary use period (41.8% Headspace; 50.0% Smiling Mind; 53.7% Control app) ($F(2,188) = .026$, $p = .975$). In fact, only 16.4% of Headspace, 15.4% of Smiling Mind, and 17.9% of the control app users reported using their app two or more times per week during that open access period; again, there were no differences between the conditions ($F(2,188) = .053$, $p = .948$).

Table 3.1.

Descriptive statistics for the demographic and baseline mental health measures for the sample overall and separately for each condition.

	Overall (*n* = 208)				Control (*n* = 73)				Headspace (*n* = 72)				Smiling Mind (*n* = 63)			
Outcome	Mean (*n*)	*SD* (%)	Min	Max	Mean (*n*)	*SD* (%)	Min	Max	Mean (*n*)	*SD* (%)	Min	Max	Mean (*n*)	*SD* (%)	Min	Max
Gender (% female)	146	70.2			53	72.6			48	66.7			45	71.4		
Ethnicity (% Caucasian[26])	162	77.9			55	75.3			59	81.9			48	76.2		
Age	20.08	2.88	18	49	19.82	1.09	18	25	20.19	3.05	18	41	20.24	3.95	18	49
Depressive Symptoms	14.77	8.82	1.00	50.00	13.36	6.99	1.00	35.00	15.56	10.00	2.00	50.00	15.52	10.00	2.00	43.00
Anxiety	6.71	4.06	0.00	17.00	6.36	3.67	1.00	16.00	6.75	4.27	1.00	17.00	7.08	4.26	0.00	17.00
Stress	17.55	6.20	2.00	33.00	17.79	6.06	2.00	30.00	16.89	6.14	5.00	33.00	18.02	6.47	5.00	31.00
Resilience	3.18	.77	1.00	5.00	3.22	.80	2.00	5.00	3.20	.72	2.00	5.00	3.09	.80	1.00	4.00
Flourishing	45.86	6.09	22.00	56.00	46.77	4.20	36.00	56.00	45.60	6.87	22.00	56.00	45.10	6.91	22.00	56.00
College Adjustment	79.96	15.30	42.00	117.00	81.02	14.07	42.00	111.00	80.27	16.77	42.00	111.00	78.40	15.02	49.00	117.00
Mindfulness	30.81	5.18	16.00	44.00	30.70	5.13	18.00	44.00	31.17	4.97	20.00	40.00	30.52	5.53	16.00	42.00
Personal Growth[a]	40.41	8.14	13.00	54.00	37.73	5.84	23.00	52.00	37.47	8.07	13.00	52.00	46.87	6.78	22.00	54.00

Note. SD = Standard Deviation. a: Personal growth was not a preregistered outcome and was included as a post-hoc exploratory measure.

[26] In this study we used 'Caucasian' as an ethnicity category to satisfy the international journal we published in. Caucasian is not an ethnicity (Mukhopadhyay, 2018) and thus in all remaining studies we use ethnicity categories as indicated by the New Zealand census. New Zealand European/Pākehā made up 73.6% of the overall study sample; results did not differ. In this study we used binary categories of male and female to represent gender. Recognising that these binary categories do not represent all people, in remaining studies, gender was open text and participants were able to provide their own description of their gender.

Table 3.2.

Descriptive statistics and one-way ANOVA for reported app usefulness and effectiveness at each time point for the sample overall and separately for each condition.

		Overall			Control			Headspace			Smiling Mind			One Way ANOVA		
Time point	Outcome	*N*	*M*	*SD*	*N*	*M*	*SD*	*N*	*M*	*SD*	*N*	*M*	*SD*	*F*	*df*	*p*
Time 0	Usefulness	208	3.22	.66	73	3.26	.58	72	3.18	.68	63	3.21	.74	.27	205	.764
	Effectiveness	208	3.05	.69	73	3.04	.56	72	3.15	.73	63	2.94	.78	.75	205	.474
Time 1	Usefulness	208	2.84	.74	73	2.53	.71	72	3.06	.67	63	2.94	.76	10.63	205	<.001***
	Effectiveness	208	2.77	.74	73	2.47	.73	72	3.00	.67	63	2.87	.73	11.16	205	<.001***
Time 2	Usefulness	191[a]	2.66	.79	67	2.46	.73	67	2.76	.84	57	2.77	.78	3.28	188	.040*
	Effectiveness	191[a]	2.66	.79	67	2.43	.72	67	2.79	.77	57	2.79	.84	4.62	188	.011*

Note: * $p < .05$, ** $p < .01$, *** $p < .001$. *M* = Mean, *SD* = Standard deviation. Scale range: 1-4.[a] = *n* = 191 for this question only, remaining Time 2 outcomes *n* = 192.

3.3.2. Changes in mental health within conditions

Table 3.3. presents the paired t-test results and descriptive statistics for the mental health measures at all three time points for the separate conditions. Headspace users reported significant reductions in depressive symptoms, anxiety, and stress, and significant improvements in college adjustment and mindfulness, but not flourishing or resilience, from baseline to the end of the 10-day period. These changes were mostly maintained until the final time point 40 days later, with the exception of depressive symptoms. Resilience showed a different pattern, exhibiting a significant increase only at the final time point, but not immediately after the 10 days for Headspace users, suggesting a possible 'sleeper effect'. Smiling Mind users reported significant reductions in depressive symptoms and anxiety, but not stress, and significant improvements in resilience and college adjustment, but not flourishing or mindfulness, from baseline to the end of the 10-day period. These changes were only maintained for anxiety and college adjustment at the final time point 40 days later. By contrast, control app users reported small but significant increase in depressive symptoms, and significant decreases in flourishing and stress from baseline to the end of the 10-day period, which were mostly maintained 40 days later.

Table 3.3.

Descriptive Statistics and paired t-tests comparing changes from Time 0 (baseline) to Time 1 (follow up) or Time 2 (final) for each condition separately.

		Time 0		Time 1		Time 2		Time 0 to Time 1				Time 0 to Time 2			
Condition	Outcome	*M*	*SD*	*M*	*SD*	*M*	*SD*	% change	Hedges' *g* (between[a])	Cohen's *d* (within[b])	*t*	% change	Hedges' *g* (between[a])	Cohen's *d* (within[b])	*t*
Headspace (Time 0 + 1 *n* = 72; Time 2 *n* = 67)	Depressive symptoms	15.56	10.00	13.00	9.38	13.63	10.22	-16.5	.23	.26	3.17**	-10.9	.17	.17	1.91
	Anxiety	6.75	4.27	5.74	4.14	5.87	4.13	-15.0	.08	.24	2.78**	-13.9	.15	.23	2.20*
	Stress	16.89	6.14	15.29	6.26	15.04	6.24	-9.5	.19	.26	3.71***	-10.8	.17	.30	3.28**
	Resilience	3.20	.72	3.28	.73	3.46	.72	2.5	-.08	-.11	-1.55	7.1	-.27	-.32	-3.44**
	Flourishing	45.60	6.87	44.58	8.90	44.57	8.12	-2.2	.08	.13	1.23	-2.6	.01	.17	1.39
	College adjustment	80.27	16.77	85.00	15.72	84.80	16.54	5.9	-.30	-.29	3.98***	6.4	-.17	-.31	-3.35**
	Mindfulness	31.17	4.97	33.03	5.58	32.54	5.45	6.0	-.34	-.35	4.62***	4.4	-.28	-.26	-2.63*
Smiling Mind (Time 0 + 1 *n* = 63; Time 2 *n* = 58)	Depressive symptoms	15.52	9.21	13.51	9.44	14.14	9.83	-13.0	.17	.22	2.25*	-8.4	.12	.13	1.25
	Anxiety	7.08	4.26	5.98	4.12	6.03	3.99	-15.5	.02	.26	3.00**	-16.7	.12	.29	2.37*
	Stress	18.02	6.47	17.02	6.61	16.62	6.62	-5.5	-.08	.15	1.68	-6.7	-.05	.18	1.72
	Resilience	3.09	.80	3.29	.73	3.23	.83	6.5	-.09	-.26	-3.89***	4.2	.02	-.16	-1.86
	Flourishing	45.10	6.91	44.40	8.12	45.09	7.97	-1.5	.12	.09	1.36	-.1	-.07	.01	.08
	College adjustment	78.40	15.02	82.32	16.57	81.91	16.12	5.0	-.12	-.25	-3.45**	4.7	.00	-.24	-2.12*
	Mindfulness	30.52	5.53	31.14	6.25	31.48	6.53	2.0	.01	-.11	-1.36	2.9	.09	-.15	-1.44
Control (Time 0 + 1 *n* = 73; Time 2 *n* = 67)	Depressive symptoms	13.36	6.99	15.05	8.47	15.43	11.40	12.7		-.22	-2.59*	19.8		-.28	-2.26*
	Anxiety	6.36	3.67	6.05	3.48	6.56	4.81	-4.9		.09	1.10	6.5		-.09	-.88
	Stress	17.79	6.06	16.52	6.40	16.27	8.14	-7.1		.20	2.68**	-6.3		.15	1.48
	Resilience	3.22	.80	3.22	.74	3.25	.80	0.0		.00	-.07	-.3		.01	.16
	Flourishing	46.77	4.20	45.21	5.68	44.51	8.79	-3.3		.31	3.10**	-5.2		.36	2.72**
	College adjustment	81.02	14.07	80.36	15.05	81.98	16.86	-.8		.05	.50	.2		-.01	-.09
	Mindfulness	30.70	5.13	31.19	5.29	30.90	6.00	1.6		-.09	-1.20	.4		-.02	-.19

4. *Note:* * $p < .05$, ** $p < .01$, *** $p < .001$. *M* = Mean, *SD* = Standard deviation. [a] = effect size comparing mindfulness app to control app 1 using Hedges' *g* = [mean intervention – mean control / pooled standard deviation]*Hedges correction factor [1-3/(4*N*-9)]. [b] = effect size within condition over time..

3.3.3. Changes in mental health between conditions

Table 3.4. presents the multiple regression results comparing changes in mental health outcomes over time between the three conditions. Users of Headspace and Smiling Mind reported significantly reduced depressive symptoms over time compared to the control group at both time points. The size of the coefficients suggested that both mindfulness apps reduced depressive symptoms by approximately 3–3.5 points (equivalent to approximately a .4 standard deviation change in depressive symptoms), bringing mindfulness app users below the cut off for significant symptoms of depression [cut off: 16; (Lewinsohn et al., 1997)]. There were no significant differences in changes in depressive symptoms between the two mindfulness app's users. Headspace and Smiling Mind users showed improvements in college adjustment at Time 1 (equivalent to approximately a .3 standard deviation change in college adjustment), but these changes did not last through to Time 2. Headspace users had significant improvements in trait mindfulness at Time 1 compared to both Smiling Mind and control app users (equivalent to approximately a .25 standard deviation change in trait mindfulness), although the trait mindfulness changes did not last through to Time 2. Finally, Headspace users had significant improvements to resilience that emerged at Time 2 (equivalent to approximately a .3 standard deviation change in resilience), but not at Time 1, compared to the control group. By contrast, Smiling Mind users reported significant improvements in resilience at Time 1 relative to the control group (equivalent to approximately a .2 standard deviation change in resilience), but this change did not last through to Time 2.

Table 3.4.

Multiple regression analysis of changes in mental health outcomes by experimental condition from Time 0 to Time 1 (left columns), and from Time 0 to Time 2 (right columns). The Time 0 outcome and expectation scores were controlled in Time 0 to Time 1 analyses. The Time 0 outcome and Time 1 perception scores were controlled in Time 0 to Time 2 analyses.

	Time 0 to Time 1				Time 0 to Time 2			
	Control	Control vs. Headspace[1]	Control vs. Smiling Mind[2]	Headspace vs Smiling Mind[3]	Control	Control vs. Headspace[1]	Control vs. Smiling Mind[2]	Headspace vs Smiling Mind[3]
Outcome	Constant (SE)	ß$_4$ (SE)	ß$_5$ (SE)	ß (SE)	Constant (SE)	ß (SE)	ß (SE)	ß (SE)
Depressive Symptoms	16.18	-3.74***	-3.35**	.39	16.42	-3.21*	-3.00*	.21
	(.72)	(1.02)	(1.06)	(1.06)	(1.02)	(1.47)	(1.48)	(1.45)
Anxiety	6.32	-.61	.62	.02	6.88	-1.05	-1.18	-.14
	(.30)	(.43)	(.44)	(.44)	(.44)	(.63)	(.64)	(.62)
Stress	16.33	-.48	.28	.77	15.96	-.36	.31	.67
	(.47)	(.66)	(.69)	(.69)	(.66)	(.95)	(.95)	(.94)
Resilience	3.19	.07	.16*	.10	3.22	.20*	.07	-.13
	(.05)	(.07)	(.08)	(.08)	(.07)	(.10)	(.10)	(.10)
Flourishing	44.38	.41	.86	.46	43.96	.61	1.82	1.21
	(.61)	(.89)	(.90)	(.90)	(.84)	(1.21)	(1.23)	(1.20)
College Adjustment	79.51	5.40**	4.09*	-1.32	81.21	3.48	1.98	-1.50
	(1.17)	(1.66)	(1.73)	(1.74)	(1.56)	(2.24)	(2.26)	(2.23)
Mindfulness	31.28	1.42*	.15	-1.27*	31.15	1.00	.51	-.49
	(.60)	(.57)	(.59)	(.60)	(.51)	(.79)	(.79)	(.78)

Note: * $p < .05$, ** $p < .01$, *** $p < .001$ [1] Dummy coded 0 (Control), 1 (Headspace), 0 (Smiling Mind), and entered with [2] dummy coded 0 (Control), 0 (Headspace), 1 (Smiling Mind). [3] Dummy coded 0 (Control), 0 (Headspace), 1 (Smiling Mind) and entered with dummy coded 1 (Control), 0 (Headspace), 0 (Smiling Mind)

3.3.4. Moderation by app use

Frequency of app use during the 10 days did not show clear patterns of moderation (Supplementary Table 3.2. and Supplementary Figure 3.3.). This is likely because usage was quite high and consistent during the 10 days (overall *M(SD)* = 8.34(1.95) days). However, app use during the 30-day discretionary period significantly moderated the effect of condition on changes in depressive symptoms, anxiety, college adjustment, and mindfulness from Time 0 to Time 2 (see Table 3.5.). Figure 3.2. also depicts this pattern of moderation by 30-day app use for depressive symptoms (panel A), anxiety (panel B), college adjustment (panel C), and mindfulness (panel D) with significant simple slopes indicated (Aiken & West, 1991). Participants who used the mindfulness meditation apps more frequently during the discretionary period showed statistically greater improvements in college adjustment [Headspace only] and mindfulness [Smiling Mind only] compared to participants who did not use the mindfulness apps as frequently or who used the control app. By contrast, participants who used the control app most frequently reported poorer mental health than those who used the control app less frequently [panels A–D], although some of these patterns were only trends.

Table 3.5.

Moderator analyses testing how app usage during the 30-day period moderated the effect of experimental condition on changes in mental health outcomes from Time 0 to Time 2. The Time 0 outcome was controlled in all analyses.

	Outcomes						
Predictors	Depressive Symptoms B(SE)	Anxiety B(SE)	Stress B(SE)	Resilience B(SE)	Flourishing B(SE)	College Adjustment B(SE)	Mindfulness B(SE)
Intercept (Control)	16.71 (.98)***	6.92 (.42)***	16.23 (.64)***	3.20 (.07)***	43.71 (.81)***	80.72 (1.48)***	30.96 (.51)***
Outcome covariate at Time 0 (centered)	.79 (.07)***	.65 (.06)***	.78 (.06)***	.73 (.05)***	.83 (.08)***	.72 (.06)***	.78 (.06)***
Dummy 1 (Control vs. Headspace)	-3.70 (1.39)**	-1.11 (.06)	-.83 (.90)	.24 (.09)*	1.01 (1.14)	4.31 (2.10)*	1.32 (.73)
Dummy 2 (Control vs. Smiling Mind)	-3.27 (1.45)*	-1.30 (.62)*	-.05 (.94)	.11 (.10)	1.94 (1.19)	2.53 (2.19)	.77 (.76)
App Usage (centered)	1.37 (.70)	.62 (.30)*	.55 (.46)	-.04 (.05)	-.36 (.58)	-2.25 (1.07)*	-.98 (.37)**
Dummy 1 x App Usage	-2.31 (1.09)*	-1.19 (.46)*	-.75 (.71)	.04 (.07)	1.71 (.89)	4.40 (1.64)**	1.65 (.57)**
Dummy 2 x App Usage	-2.25 (1.09)*	-.93 (.46)*	-.95 (.71)	.08 (.08)	.90 (.90)	3.04 (1.65)	2.00 (.57)**
Intercept (Headspace)	13.01 (.98)***	5.81 (.42)***	15.41 (.64)***	3.44 (.07)***	44.73 (.80)***	85.03 (1.48)***	32.28 (.52)***
Outcome covariate at Time 0 (centered)	.79 (.07)***	.65 (.06)***	.78 (.06)***	.73 (.05)***	.83 (.08)***	.72 (.06)***	.78 (.06)***
Dummy 2 (Headspace vs Smiling Mind)	.43 (1.44)	-.19 (.61)	.78 (.94)	-.13 (.10)	.92 (1.19)	-1.78 (2.19)	-.54 (.76)
Dummy 3 (Headspace vs Control)	3.70 (1.39)**	1.11 (.59)	.83 (.90)	-.24 (.09)*	-1.01 (1.14)	-4.31 (2.10)*	-1.32 (.73)
App Usage (centered)	-.94 (.82)	-.56 (.35)	-.20 (.54)	.00 (.06)	1.36 (.68)*	2.15 (1.25)	.67 (.43)
Dummy 2 x App Usage	.06 (1.12)	.26 (.50)	-.20 (.76)	.04 (.08)	-.81 (.96)	-1.36 (1.77)	.35 (.62)
Dummy 3 x App Usage	2.31 (1.09)*	1.19 (.46)*	.75 (.71)	-.04 (.07)	-1.71 (.89)	-4.40 (1.94)**	-1.65 (.57)**

Note: * $p < .05$; ** $p < .01$; *** $p < .001$. Dummy Code 1 = 0 (Control), 1 (Headspace), 0 (Smiling Mind). Dummy Code 2 = 0 (Control), 0 (Headspace), 1 (Smiling Mind). Dummy Code 3 = 1 (Control), 0 (Headspace), 0 (Smiling Mind).

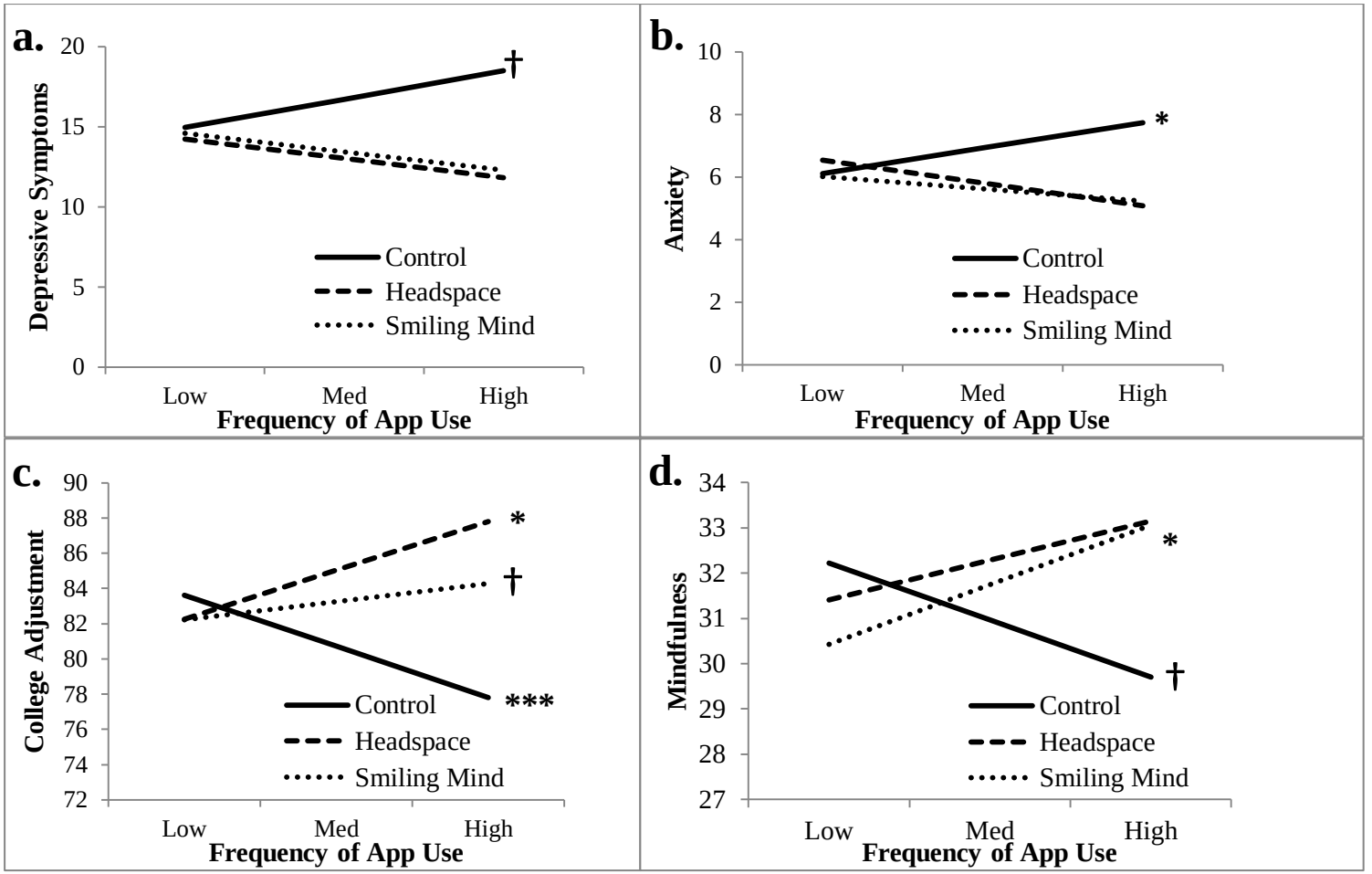

Figure 3.2. **The relation between frequency of app use during the 30-day self-directed use of app and mental health scores (a: depressive symptoms, b: anxiety, c: college adjustment, d: mindfulness) for control, Headspace, and Smiling Mind app users at Time 2 (after 30 days) controlling for time 0 mental health scores.**
Note. Frequency of app use was modelled around -1SD, +1SD, for Low, Med, and High app frequency. Depressive Symptoms scores can range between 0 – 60 with higher scores indicating higher symptoms of depression; Anxiety scores can range between 0 – 21 with higher scores indicating greater symptoms of anxiety; College Adjustment scores can range between 19 – 133 with higher scores indicating greater college adjustment; Mindfulness scores can range between 12 – 48 with higher scores indicating greater mindfulness. † $p < .10$, * $p < .05$, ** $p < .01$, *** $p < .001$

3.3.5. Post-hoc exploratory predictors of (self-reported) app use

No baseline demographic or mental health characteristics were correlated with self-reported app use during the 10-day period (where adherence was requested) nor during the 30 days (where app use was at the discretion of the participant). But several personality factors predicted self-reported app use. When including data from all participants who were randomised to a mindfulness condition (Time 0, n = 135[27]), those higher in extraversion, agreeableness, and openness reported completing *fewer* app sessions during the 10-day trial (r = -.182, p = .034, r = -.189, p = .028, and r = -.173, p = .012, respectively). By contrast, those higher in conscientiousness reported completing a greater number of app sessions during the 10-day trial (r .191, p = .027), although this did not extend to the 30 days where use was at the discretion of the participant. Only the emotional stability subscale of the *Ten Item Personality Inventory* (Gosling et al., 2003) predicted app use during the 30 days where use was at the discretion of the participant (r = .180, p = .027), with people higher in emotional stability using their app more than people lower in emotional stability.

3.3.6. Post-hoc analyses of exploratory interest variables

There was a statistically significant baseline difference in the tendency to want to change or grow (PGIS, Robitschek, 1998) between conditions (F(2, 205) = 39.02, p <.001) such that participants randomised to use Smiling Mind reported higher tendency toward wanting to change (M = 46.87, SD = 6.78) than those randomised to Headspace or Evernote (Headspace M = 37.47 SD = 8.07 and Control M = 37.73 SD = 5.84) at Time 0. Users of Headspace (but not control app users) reported significantly increased tendency to seek change or growth over time (paired t-tests Time 0-Time 1; Time 0 – Time 2), whereas users of Smiling Mind reported significantly decreased tendency to seek change or growth over time (paired t-tests Time 0-Time 1; Time 0 – Time 2). When Time 0 PGIS (mean centered) was added to the regression equations at Time 1

[27] Here, I am interested in what predicts use of mindfulness apps. Nevertheless, these findings held when all participants (i.e., n = 210, including attention controls) were included albeit the correlations were weaker (rs -.173 - .155, ps = .012 - .038) and agreeableness no longer predicted app use (r = -.106, p = .125).

and Time 2 (along with the mean centered baseline outcome variable and expectation scores [for analyses at Time 1] and perception scores [for analyses at Time 2]), the original effects of mobile mindfulness app use on mental health outcomes only held for Headspace users, suggesting that factors beyond introductory mindfulness content may also be impacting these associations. See supplementary table 3.4.

3.4. Discussion

In line with our hypotheses, mindfulness meditation app users reported greater improvements in several mental health outcomes than did attention-placebo control app users. The improvements varied by the mindfulness app, timeframe, frequency of use, and reference point (i.e., comparing to self-baseline vs. comparing to control app users) but the results provide preliminary evidence of the mental health utility of mobile mindfulness meditation apps, which warrants further investigation. The most consistent improvements were observed for depressive symptoms and college adjustment, where both Headspace and Smiling Mind users reported small but significant improvements after 10 days of requested app use relative to the control condition. These improvements may represent a clinically meaningful change given that a 3–3.5 point change in depressive symptoms brings mindfulness app users under the cut-off for significant symptoms of depression, unlike the control app users. This change in depressive symptoms relative to control was further maintained after 30 days of discretionary use. Thus, our patterns for depressive symptoms replicated the work of Bostock et al., (2019) and Howells et al., (2016) who also found reductions in depressive symptoms after Headspace mindfulness meditation app use.

Changes in mental health outcomes were also associated with frequency of app use. People who used their mindfulness apps more frequently during the 30 days of discretionary use showed the greatest benefits in terms of their college adjustment and mindfulness. Importantly, this benefit for frequent app users only occurred for those randomly assigned to use a mindfulness app, suggesting that the mental health benefits of mobile mindfulness apps were not explained by digital placebo effects. By contrast, users of the control app, Evernote, reported mostly poorer mental health outcomes with more frequent use. I am not sure what explains this finding.

Although it is possible that excessive 'organisational reminiscing' across an extended period of time could have triggered rumination or an awareness of unmet goals, which could be distressing, it could also simply be that the more people use an ineffective tool, the worse they feel—because the tool is not designed to improve mental health. Either way, the patterns suggest that the Evernote app might not have been a completely neutral control condition. Although this does not take away from these findings, it suggests that Evernote should be considered an attention control but not an attention *placebo* control and that future research should carefully consider the nature of the control condition.

When looking at the secondary pre-registered outcomes, mindfulness practice was associated with increasing adjustment to college life after 10 days of requested app use. But there were inconsistent improvements in resilience across the two mindfulness apps over time. Smiling Mind users reported immediate but not sustained improvements in resilience, whereas Headspace users reported a lagged improvement in resilience after the 30-day discretionary use period. Previous research has linked mindfulness with increases in adaptive stress responses and coping resources (Weinstein, Brown, & Ryan, 2009). Given that the transition to college life can be tumultuous (Fisher & Hood, 1987) and young adults are heavily reliant on their mobile phones (Oliver, Pearson, Coe, & Gunnell, 2005; Smith, 2017), mobile mindfulness may present a promising tool to improve adjustment to college life, build resilience, and enhance the ability of incoming college students to cope with stressors. Thus, these findings may have valuable applications for colleges that are implementing mindfulness programmes (Swain, 2016).

Mobile mindfulness users did not report significant changes in flourishing. Improvements in trait well-being can be extremely difficult to achieve (Weiss, Westerhof, & Bohlmeijer, 2016). Therefore, the low-intensity of this intervention (i.e., 10-minute meditations, once a day) may not have been sufficient to produce changes in flourishing.

Changes in mindfulness were much less consistent than the other mental health measures. Interestingly, Headspace users showed sustained small increases in mindfulness over the course of the intervention (at least as I measured it, using the Cognitive and Affective Mindfulness Scale – Revised; (Feldman et al., 2006), whereas Smiling Mind users did not (although more frequent

users of Smiling Mind were equivalent in mindfulness to more frequent users of Headspace at the end of the 30-day discretionary period, as shown in Figure 3.2. panel D). Given that both apps provide similar introductory mindfulness training *content* (e.g., body scan, breathing exercises), I believe that *individual differences* and differences in the app *interface* may be responsible for any observed differences here. In post-hoc exploratory analyses, when I controlled for baseline differences in the 'tendency to want to change' (as measured by the Personal Growth Initiative Scale, Robitschek, 1998), Smiling Mind no longer had an effect on mental health outcomes. Previous research has established that interactive, beautiful, and well-designed apps are more appealing and encourage more loyalty from their users (Cyr, Head, & Ivanov, 2006). In ongoing research I am qualitatively addressing questions about differences in user experience with Headspace and Smiling Mind app users where initial themes suggest interface differences influenced participant willingness and ability to use the apps[28]. Although the exploratory analysis should be interpreted with caution, in combination, these findings lend weight to the idea that not all mindfulness apps are created equally. On the basis of the planned analyses and these additional findings, I deemed Headspace to be the more impactful intervention[29].

Finally, although I attempted to investigate the notion of a digital placebo effect (Torous & Firth, 2016) by implementing an attention placebo control condition, control participants did not report that their app was as useful or effective as the mindfulness apps, suggesting that this was not an adequate comparison condition to tease apart the relationship between app use in general and the therapeutic benefits of mindfulness, specifically. Nonetheless, when controlling for participants' expectations (Time 0 to Time 1) and their subsequent perceptions following use of their apps (Time 0 to Time 2), I still found some improvements in mental health (namely, depressive symptoms at both time points and college adjustment at Time 1 only).

[28] I conducted 9 focus groups with 5 Headspace and 2 Smiling Mind (and 2 control group) participants. These focus groups were used to identify implementation barriers and to assess acceptability of mobile mindfulness. These qualitative analyses are ongoing but the method and question schedule are available in Supplement 3.5. Initial themes were used to inform the development of Studies 2 and 3.

[29] Smiling Mind has subsequently been redesigned with substantial additional content added, therefore, additional research is required to establish whether Smiling Mind in its current design is equivalent to Headspace.

3.4.1. Limitations and additional considerations

Although this study had high ecological validity, this validity came at the cost of strict control over app adherence. While the drop-off in self-reported app-use during the 30-day discretionary period was particularly high across conditions, this drop off is typical of naturalistic use of these types of tools (Aitken & Lyle, 2015; Farago, 2012) and was in line with our hypotheses. Given the high drop off, the fact that some changes in mental health outcomes held is reassuring in light of the short follow-up times in previous research (Ahtinen et al., 2013; Carissoli et al., 2015; Howells et al., 2016; Lim, Condon, & DeSteno, 2015). Even so, experts have suggested that "mindfulness is simple, but not easy" (quote attributed to Jon Kabat-Zinn by Segal, 2003, in Sears, Kraus, Carlough, & Treat, 2011), therefore, continued practice of mindfulness may be necessary to fully reap the benefits (Bergomi, Tschacher, & Kupper, 2015).

In correlational post-hoc analyses, I identified that those higher in extraversion, agreeableness, and openness were less adherent (i.e., reported completing *fewer* app sessions) when their adherence was requested (i.e., during the 10-day trial), and that those higher in emotional stability reported completing more sessions during the 30-day trial where adherence was at their discretion. These findings for extraversion and emotional stability are consistent with prior work by Wahbeh, Goodrich, and Oken (2016) who found that extraverted people preferred group-based meditation training rather than online training, while emotionally stable people preferred online mindfulness training over group-based training. In this respect, face-to-face delivery of mindfulness instruction may provide a superior social environment for some new mindfulness practitioners (Segal et al., 2013).

It is also a concern that the very people who might benefit most from mindfulness practice—emotionally *un*stable people—were the least likely to use the apps during the discretionary use period. Although we were underpowered to analyse this further, some research suggests that despite generally favourable attitudes towards meditation, mindfulness, and relaxation apps (ranked #1) by mental health service users, there is a substantial minority (around one-third) who report no positive attitude toward *any* mental health apps (Dragovic et al., 2018).

Taken together, this suggests it may be challenging to encourage uptake of these apps among a subset of the more vulnerable individuals. But apps are not the only digital options. Web- and email-based mindfulness programmes are also being developed to meet the needs of those not being served by resource-intensive face-to-face courses (see: (Spijkerman et al., 2016) for review and meta-analysis of web-based mindfulness programmes). Further, when a health app is prescribed by a health provider (e.g., doctor, counsellor), 30-day retention rates typically increase by 10–30% (Aitken & Lyle, 2015).

Other limitations are related to the sample demographics and size. Our sample was ostensibly made up of healthy undergraduate students, meaning I cannot extrapolate the current findings to a clinical sample. Nevertheless, there were still people in the sample with some mental health challenges. Although average depressive symptom scores fell below the commonly accepted cut-off, almost 40% of this sample was above the cut-off at baseline. This substantial minority with high depressive symptoms suggests that young adults not recruited through a mental health clinic setting still have issues related to mental health. Nonetheless, it is still an outstanding question whether mobile mindfulness apps could be useful in a patient population either as an adjunct-to-treatment or as a suitable homework component in therapy to facilitate the treatment of patients with anxiety and depressive symptoms (Kladnitski, Smith, Allen, Andrews, & Newby, 2018; Price et al., 2014) although this remains to be tested. Importantly, further research on the adverse effects of apps replacing or complementing TAU is necessary; although not specific to app-based mindfulness, this topic is beginning to receive attention (e.g., see: Stevens, van der Sande, Beijer, Gerritsen, & Assendelft, 2019)/

Further, while the sample size was higher than most previous mobile mindfulness research it was still underpowered to detect between group differences. Future researchers should consider using more conservative effect size estimates when conducting their power analyses. Our strongest effect sizes in depressive symptoms (g = .23) were, in general, smaller than those found in previous research on mobile, web-based, and face-to-face mindfulness meditation programmes (Howells et al., 2016); a single study of mobile mindfulness, g = .35 (Spijkerman et al., 2016); a meta-analysis of web-based mindfulness, g = .29 (Goyal et al., 2014); and a meta-analysis of face-

to-face mindfulness, d = .30). Nevertheless, given the brevity and ease of implementation, the reported mental health improvements may still represent meaningful change for those experiencing them and clinically meaningful change where app users move further from established cut-off points (e.g., those used to suggest experience of clinically significant experience of depression (Lewinsohn et al., 1997)).

Our reliance on self-reported app use and psychological outcomes may also have led participants to over- or under-estimate their app use during the discretionary period and their responses may be subject to a number of response biases (e.g., social-desirability bias). I initially asked Headspace and Smiling Mind if they would be able to provide objective app use, but both parties declined (Headspace did not wish to be involved in a competitive trial and Smiling Mind cited privacy concerns). Nevertheless, given our preliminary evidence that (self-reported) app use moderated the effect of the intervention on the outcomes, it could be important to establish that self-reported app use is an accurate representation of objective use.[30] Where possible, researchers should design their protocol to collect objective measures of app usage. Attempts to measure trait mindfulness via self-report are also being challenged by researchers (e.g., Van Dam et al., 2017); as such, future researchers should consider collecting more objective behavioural measures to support their self-reported measures (e.g., breath counting; Levinson, Stoll, Kindy, Merry, & Davidson, 2014).

Finally, to establish compelling evidence for the effectiveness of mobile mindfulness meditation, in the future, researchers should investigate mindfulness-based apps as stand-alone vs. adjunct-to-treatment as usual, and should compare mindfulness-based apps to not only established mindfulness meditation programmes (e.g., MBSR, Kabat Zinn, 1982) but also to other digital modalities (e.g., web- or email-based mindfulness) and to active app-based controls. For instance, given our modest findings of small improvements in depressive symptoms, there would be merit

[30] In a subsequent replication of this research protocol (using Headspace, Evernote and an email-based mindfulness programme called the 10 Minute Mind, instead of Smiling Mind) the developers of the mindfulness programmes agreed to provide objective use data. Here, we established that self-reported adherence–whether reported daily, or retrospectively–was not an adequate representation of app-based intervention adherence. This published article is available in Supplement 3.6: Flett, J. A. M., Fletcher, B. D., Riordan, B. C., Patterson, T., Hayne, H., & Conner, T. S. (In Press). The peril of self-reported adherence in digital interventions: a brief example. *Internet Interventions*.

in comparing mindfulness meditation apps to a web- or email-based brief mindfulness programme to establish whether the effects of digital mindfulness are modality specific.[31] Another option for future research would be to compare mobile mindfulness apps to an evidence-supported cognitive-behavioural therapy (CBT) app. Doing so would allow us to establish whether there is non-inferiority or superiority to an established treatment modality such as CBT, when delivered by mobile phone. Although this area too, is in its infancy (Torous, Levin, Ahern, & Oser, 2017).

3.4.2. Conclusion

Here, I presented preliminary evidence that use of a mobile mindfulness app, Headspace, can improve some mental health outcomes in a non-clinical student population. While I cannot take these findings to mean that all mobile mindfulness apps are created equal—nor do I suggest that they should replace traditional face-to-face mindfulness programmes—this study serves as the rationale for the remaining studies presented in this thesis which use Headspace as a brief intervention in targeted student populations. In Chapters 3 and 4, I describe two targeted mobile mindfulness interventions using Headspace. In the first, building on the current findings of impact on depressive symptoms, I targeted a distressed student population who were accessing the University of Otago's Counselling Service. In the second, building on the current findings of impacts on college adjustment and resilience, I targeted an incoming university student population during their transition to university.

3.5. Acknowledgements

I would like to thank and acknowledge the input of Laura Thompson, Ben Riordan, Tayla Boock, Todd Johnston, and Samantha McDiarmid for their assistance collecting data on Study 1. I would also like to thank the students who took time out of their busy lives to take part in this

[31] As described earlier, in a subsequent replication of this research protocol we compared Headspace (app-based mindfulness) to the 10 Minute Mind (email-based mindfulness) with the intention of addressing this issue. Unfortunately, objective use of the mindfulness programmes was so low that we reported null results for the intervention. This replication was conducted after Studies 1, 2, and 3 presented in the current thesis. See Supplement 3.6. for more detail: Flett, J. A. M., Fletcher, B. D., Riordan, B. C., Patterson, T., Hayne, H., & Conner, T. S. (In Press). The peril of self-reported adherence in digital interventions: a brief example. *Internet Interventions*.

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CHAPTER 4: STUDY 2

Mobile mindfulness meditation as an adjunct to treatment-as-usual: A pragmatic randomised waitlist-controlled trial

4.1. Overview and Rationale

4.1.1. Prevalence of mental health issues in university students

The mental health needs of university students are growing. Almost one-third of all first-year university students surveyed as part of the WHO International College World Mental Health Survey reported a history of at least one common DSM-IV mood, anxiety, or substance disorder (n = ~14,000 across 8 countries; Auerbach et al., 2018). While this rate is higher than earlier WHO estimates (1 in 5 based on face-to-face interviews with 1572 university students across 21 countries [including New Zealand Aotearoa]; Auerbach et al., 2016) and lower than some country-specific estimates (1 in 2 young adult college students in the USA, N = 2188; Blanco et al., 2008), it is consistent with a survey conducted by the New Zealand Union of Students' Associations (NZUSA; Gharibi, 2018). The increased prevalence and the severity of mental health needs among university students is, in turn, driving the growing demand for mental health services within tertiary institutions.

4.1.2. Demand for university mental health services are higher than ever

Universities New Zealand (UNZ; a representative of all universities in Aotearoa New Zealand), recently reported that mental health services are facing a "here-and-now tsunami of need that is not being met" (Universities New Zealand, 2018, p.15). Consistent with this message, Dr. Kim Ma'ia'ia (former Director of Student Health Services at the University of Otago, and advisor on this project) reported to the University of Otago's *Critic te Arohi* magazine that "a five year increase in levels of student distress has almost become a new normal," and that all Health Service providers would be struggling to meet the increased demand (Higham, 2017, para. 4). Using data requested under the Official Information Act (1982), NZUSA reported an almost 25% increase in the number of students using university counselling services, and a 10.5% increase in

the number of counselling sessions per 1000 students between 2015 and 2017 (Smith, 2018). Unsurprisingly, the demand for university mental health services was described as "untenable" by UNZ Executive Director, Chris Whelan (Redmond, 2018).

The high demand for mental health services means wait times are also a serious concern (Universities New Zealand, 2018). Despite almost half of students reporting that they only used one or two counselling sessions (n = 328/705), over 30% also reported that they had to wait for two weeks or longer to get an appointment (n = 239/718) and that long wait times were a key self-reported reason for not accessing services (Gharibi, 2018).

The increasing demand for student mental health services is not unique to Aotearoa New Zealand. In the United States of America, a 6% increase in student enrolment over a 5-year period was associated with a 30% increase in treatment seeking (Xiao et al., 2017). Likewise, rates of diagnosed mental health conditions in a large sample of college students increased by approximately two-thirds and service utilization increased from 19-34% between 2007-2017 (N =155026; Lipson, Lattie, & Eisenberg, 2019). Further, only 4% of counselling centre Directors reported that caseload demand was not an issue (Smith et al., 2007), and over 30% of counselling centres required a waitlist ($M_{\text{first appointment}}$ = 17.7 days) in order to manage their client load (N = 571 college counselling centres; LeViness, Bershad, Gorman, Braun, & Murray, 2018).

An obvious answer to counteract the increasing demand for mental health services is to provide more services, but this is not always feasible or affordable in a complex institution like a university. Although broader mental health funding in Aotearoa New Zealand has increased almost four-fold from $1.1 billion to nearly $4 billion between 2008/2009 and 2015/2016 (Mulder, Rucklidge, & Wilkinson, 2017), universities, by comparison, are severely constrained by the student services levies used to fund university health services (Redmond, 2018). This funding constraint has unique implications for mental health services because unlike all other health services provided by universities (which are subsidised by the government), mental health services are 100% funded by the university (Universities New Zealand, 2018). With this in mind,

in their submission to the Government's 2017 Mental Health and Addictions Inquiry, UNZ appealed to the government to better fund community mental health and specialist mental health services so that university mental health services can prioritise their limited resources to manage mild to moderate cases more successfully. UNZ also underscored for the need for a stronger focus on prevention, early intervention, and reducing wait times so that mild to moderate cases do not escalate (Universities New Zealand, 2018).

4.1.3. Incorporating digital services to help meet the increased demand for mental health services

Accessing the appropriate treatment and receiving the necessary support is essential for people experiencing psychological distress, and delays may lead to worsening distress. Given the strain on resources and increasing wait times to access services, university mental health services are beginning to incorporate digital technology as part of normal service delivery (e.g., for screening, health promotion, and delivering interventions; Johnson & Kalkbrenner, 2017; LeViness, Bershad, Gorman, Braun, & Murray, 2018). Digital interventions are often suggested as a cost-effective way to help address wait times, and to increase access to evidence-based treatment (Mohr, Burns, Schueller, Clarke, & Klinkman, 2013). Although the addition of digital services introduces new challenges (e.g., implementation of new technologies and sustainability of use after the initial excitement wears off; Greenhalgh et al., 2017; Mohr, Lyon, Lattie, Reddy, & Schueller, 2017), they may also help overcome other existing barriers (e.g., prolonged wait times, stigma, and barriers to accessibility; Renton et al., 2014) and meet the increased demand for mental health services. Importantly, digital services can also be used as tools within the therapeutic process to compliment other treatments, or as part of ongoing management.

4.1.4. App-based mindfulness interventions as a potential digital intervention

Mindfulness meditation is a common group-therapy for clinical mental health (National Institute of Health and Clinical Excellence, 2009). Although group-based mindfulness interventions like MBSR and MBCT are well-established treatment options in clinical populations

and student populations (refer to sections 1.3. of Chapter 1: Literature review), the evidence for briefer app-based mindfulness programs in clinical populations is non-existent. Despite the lack of existing evidence, commonly held views are that mindfulness apps may be well-suited to students who are accessing counselling services. For example, in a survey of Australian mental health consumers and clinicians, both consumers and clinicians ranked apps that use mindfulness, meditation and relaxation as the number 1 app they would be willing to use for mental health (or in the case of clinicians, the app they perceived consumers would be most willing to use). Over two-thirds of mental health consumers reported that mental health apps "could be useful and might improve the treatment of mental health problems" (Dragovic et al., 2018, p.4). Although evidence in clinical populations is lacking, there is accumulating evidence that brief, online, and self-help based mindfulness programs are associated with improvements in mental health (e.g., Cavanagh, Strauss, Forder, & Jones, 2014), some have also suggested that "MBIs may be an appropriate intervention for students waiting for counselling services" (Halladay et al., 2019; p.411). In non-clinical student populations, app-based mindfulness training has been associated with improvements in symptoms of depression, resilience (Study 1), stress, and mindfulness (Lyzwinski, Caffery, Bambling, & Edirippulige, 2019; Yang et al., 2018).

4.1.5. Assessing the impact of digital interventions on complex populations in university mental health services

Looking more broadly at digital mental health interventions, cumulative evidence from systematic reviews and meta-analyses suggest that web-based digital interventions can have small-to-moderate effects on a range of clinical mental health conditions including depression and anxiety (Firth, Torous, Nicholas, Carney, Pratap, et al., 2017; Firth, Torous, Nicholas, Carney, Rosenbaum, et al., 2017), but, these reviews generally conclude that further research is necessary to strengthen these findings. Despite favourable evidence for the effectiveness of digital interventions under ideal research conditions, these interventions are not often effective in routine care. For example, in a large trial conducted by the NHS, two well-established cCBT interventions (Mood Gym and Beating the Blues) in conjunction with treatment-as-usual were not

associated with any benefits over usual-care at 4-month follow-up (Mohr, Lyon, et al., 2017). Likewise, in the USA, Kaiser Permanente (a large healthcare organisation) were unsuccessful at implementing Beating the Blues several times over (Mohr, Lyon, et al., 2017). In both examples, patients did not use the tools, clinicians and providers were uncertain of how to best engage the patients, and they were unable to successfully integrate the digital interventions into the existing system (Mohr, Lyon, et al., 2017). These findings suggest that digital interventions in real-world and clinical settings may not be as feasible, practical or effective as would be suggested by the RCTs that initially established their efficacy.

So, how can we overcome the challenges of using digital interventions (including app-based mindfulness) in complex settings like a university mental health service? First, it is essential to consider how to embed the intervention into existing practices without unnecessarily burdening the clinical staff and their existing procedures (Mohr, Weingardt, Reddy, & Schueller, 2017). One way to overcome this issue is to involve the clinical staff in the design phase of the trial and to iteratively pilot and build the intervention using their expert domain knowledge (Sligo, Roberts, Gauld, Villa, & Thirlwall, 2019). This approach involves including clinical staff in deciding what the clinically meaningful outcomes of change are and how to interact with participants (Mohr, Lyon, et al., 2017; Sligo et al., 2019). Another strategy common in successful public health interventions is to recruit a "local champion" who is already in place within the system and who will act as the primary point of contact with frontline staff to allay their concerns and encourage their involvement in the research trial (Greenhalgh et al., 2017; Whelan et al., 2014). Second, it is important to consider non-specific intervention factors (factors common to all interventions) that may also impact the outcomes measured in the intervention. One particularly important factor to consider is the existing therapeutic alliance with the clinician. Therapeutic alliance is the strength of the relationship between the clinician and the client (in both directions). Therapeutic alliance is thought to be one of the strongest intervention non-specific effects impacting treatment outcomes (Flückiger, Del Re, Wampold, & Horvath, 2018) and some evidence indicates therapeutic alliance impacts outcomes in MBIs and digital interventions (Bowen & Kurz, 2012; Goldberg et al., 2013; Henson et al., 2019). Finally, it is important to

consider the long-term intention of the intervention. Many RCTs limit inclusion to the 'perfectly unwell', i.e., those with a single discrete diagnosis. But, co-morbidity is the rule, not the exception. In fact, some estimates suggest that patients who meet the inclusion criteria for psychotherapy research represent only about 20% of the overall population receiving services (Westen, Novotny, & Thompson-Brenner, 2004). It also takes a long time for research to move into practice (on average 17 years for less than 15% to become commonplace, Balas & Boren, 2000). With this in mind, and to paraphrase the CONSORT guidelines for pragmatic trials, if the ultimate goal of an intervention is for it to be usable outside of strict research settings, the ultimate test of that intervention will be in the context of the intended settings, using broader inclusion criteria to better represent the intended population of intervention users, and with little researcher interference (Zwarenstein et al., 2008).

4.1.6. The Current Study

With this background in mind, Study 2 was a targeted, pragmatic, randomised, wait-list controlled trial with a complex research design whereby students presenting at the University of Otago's Student Health Services Counselling Service were given the option of trialling a mobile mindfulness meditation app in addition to treatment as usual. The mobile mindfulness app was provided for use at one of three time points in relation to their counselling treatment:

> *Pre-counselling:* Distressed students were provided with access to the tool in the interim between triage (presentation at the counselling service) and onset of treatment (typically 3-5 weeks) to use at their discretion.
>
> *During-counselling (at onset):* Distressed students were provided with access to the tool to use at their discretion at the onset of treatment.
>
> *Post-counselling:* Distressed students were provided with access to the tool to use at their discretion at the end of treatment (Waitlist control).

Treatment plans differed for each patient who presented at the Counselling Service. Some patients received only one counselling session, whereas others received repeated sessions. The time between sessions was also patient-dependent. This situation created a complicated environment in which to conduct research. To overcome these obstacles, I extensively consulted with clinicians to iteratively "build" a research design that would consider challenges related to ethics, duty of care,

patient privacy, and clinician burden and that best worked within their existing practices, while still providing clinically meaningful data.

Setting and Consultation with Clinicians

University of Otago's Student Health Service is an on-campus health facility that provides a broad range of primary health care services to the students of the University of Otago. Student Health Services has approximately 50 staff, including nurses, general practitioners, counsellors/clinicians, and administrative staff. In 2017, these staff supported the health needs of over 18,000 FTE students (University of Otago, 2019). Participants for this study were recruited from the Counselling Service by the clinicians working there. Although the number of clinicians changed over the course of this study, at all times there was approximately 10 clinicians working either part-time or full-time to support the mental health needs of the student population. The clinicians were primarily trained as psychotherapists (but also included other counselling degrees such as community psychology, counselling psychology, and clinical psychology). The onset of this trial coincided with a change of service provision; the counselling service moved from offering unlimited counselling sessions to offering up to 6 sessions per students (this rule, however, was flexible). As an indicator of service provision, the counselling service provided 197 counselling sessions in March 2017 (number acquired through personal communication with Margaret Perley, Operations Manager).

Dr. Kim Ma'ia'i, the (former) Director of Student Health Services (SHS) and advisor on this PhD, initially proposed to Prof. Harlene Hayne (in her role as Vice-Chancellor of the University of Otago) that app-based mindfulness should be trialled as part of service provision at SHS. Prof. Hayne approached my co-supervisor (A. Prof. Tamlin Conner) seeking a PhD student interested in digital health; I was selected. Dr. Ma'ia'i suggested Jodie Black, a clinical psychologist on the counselling team at SHS, as a possible "local champion". I met with Jodie and later with Dr. Ma'ia'i and the leader of the counselling team, Mark Chignell, to discuss the current practices, services, and work environment at SHS to better understand how the research trial could fit into their practice with as little interruption as possible. I then made initial contact

with the remainder of the frontline clinicians at SHS over email and introduced myself and my proposed research. Subsequent to the initial introduction, I arranged an informal meeting with all the clinicians at SHS where we brainstormed and discussed research ideas, barriers that they foresaw, and what would be important clinical outcomes from their perspective. From there, I proposed a research design that was designed to answer questions they had (e.g., "at what stage of the counselling treatment would this tool be most useful to patients?"), in addition to the questions that I was most interested in (e.g., does a mMBI reduce psychological distress in a clinical population). This research design was refined through several further meetings with either the whole SHS counselling team or Jodie Black. I continued to pragmatically improve the implementation of the design with ongoing feedback from the clinicians to reduce their burden.

Planned Research Questions and Hypotheses

The current study was designed to answer the following research questions and hypotheses. All research questions were established in consultation with the Counselling team and build on the findings Study 1 as well as the gaps identified in the literature in 2015.

1. How does participation in a mobile mindfulness programme relate to reduction in psychological distress (and secondarily improved psychological well-being) when delivered to a distressed adult student population?

   H1: Access to an app-based mindfulness practice will be associated with reduced psychological distress (and secondarily improved psychological well-being) amongst a distressed adult student population when compared to those who do not have access to the app.

   H2: There will be a 'dose-response relationship' between app-based mindfulness meditation practice and reduced psychological distress (and secondarily improved psychological well-being). That is, among those with access to the app, those who use the app the most frequently will reap the greater benefits.

2. Does the effectiveness of a mobile mindfulness programme amongst a distressed adult student population vary based on time of intervention delivery in relation to treatment-as-usual?

   H3: Intervening before and during treatment will reduce psychological distress and possibly decrease the length of treatment sessions with the clinician (min = 1; max = 6) required by participants, compared to intervening after treatment.

3. Is the reduction in psychological distress (and secondarily improvement in psychological well-being) (as a result of increase mindfulness practice) mediated by psychological expectancies or therapeutic alliance with the clinician?

    H4: Psychological expectancies and therapeutic alliance with the clinician will mediate the relationship between app-based mindfulness and psychological distress (and secondarily psychological well-being).

A Forewarning

Unfortunately, I was unable to collect sufficient data to conduct the planned analyses regarding the effectiveness of mobile mindfulness in this population (H1- H4). This may have been due to the complex population (clinically distressed students), the complex problem (broadly defined clinical distress), the complex environment (a dynamic counselling service) in which this research was conducted, or a combination of these and other factors. Even so, I was able to capture a "snapshot" of the population of distressed university students who were willing to trial mobile mindfulness meditation. With this in mind, in this chapter, I will outline the planned research protocol before summarising the recruitment data and characteristics of the distressed participants who registered willingness to trial an innovative intervention. I will then discuss the successes and failures in design, recruitment, and participant retention. Finally, I will make suggestions for how to better implement future studies in these complex settings.

4.2. Method

4.2.1. Design

This study consisted of a pre-registered, three-arm, pragmatic, randomised, waitlist, controlled trial (pRWCT)[32]. In the study, I investigated the effect of a mobile mindfulness meditation app on changes in mental health in a distressed adult student population who have been accessing the counselling service at their local student health service. The trial and subsequent amendments were approved by the Health and Disability Ethics committee (Trial number 16/NTB/105). The trial and outcome measures were registered prior to recruitment with

[32] As a pRWCT, this research design was subject to intensive consultation with Clinicians which resulted in several iterative design changes over the course of the trial. Where deviations from the original protocol occur, I provide extensive details and justification for these changes.

the Australia and New Zealand Clinical Trials Registry (ACTRN12616000634471). The pre-registered mental health outcome measures were K10 distress (primary outcome), depression, anxiety, perceived stress, resilience, flourishing, and mindfulness. All participants were asked to download and integrate the mindfulness meditation app into their daily routine for 30 days. Participants received 30 days' access to the app based on their random assignment (stratified by gender; conditions 1:1:1 ratio; see Supplement 4.1. for further detail) into one of three conditions relating to the phase of their counselling treatment:

> *Pre-counselling:* Distressed students were provided with access to the tool in the interim between triage (presentation at the counselling service) and onset of treatment (typically 3-5 weeks) to use at their discretion.
>
> *During-counselling (at onset):* Distressed students were provided with access to the tool to use at their discretion at the onset of treatment.
>
> *Post-counselling:* Distressed students were provided with access to the tool to use at their discretion at the end of treatment (Waitlist control).

Participants were not informed which condition they were randomly assigned to at the beginning of the study. Due to the nature of the intervention, participants were otherwise not blinded to the intervention (that is, by virtue of receiving an email inviting them to download Headspace, participants would have been aware that they were assigned to a specific condition). Other than during recruitment by their clinician, all aspects of this study occurred via automated mobile or email messages. All participants were asked to answer surveys of mental health outcomes at several time points[33]:

> *Baseline survey:* Immediately following provision of consent (typically soon after their initial session with a triage clinician).
>
> *First-counselling survey:* At the beginning of their formal counselling treatment (as indicated by their clinician).
>
> *Post-counselling survey:* At the end of their formal counselling treatment (as indicated by their clinician).
>
> *Brief follow up:* A brief two-minute survey was sent at the end of the academic year.

[33] Please note that an additional survey was initially sent out to participants two weeks after receiving access to Headspace. These surveys were abandoned on 12/04/2017 (as approved by the Health and Disability Ethics Committee [16/NTB/105/AM01) to reduce participant burden and to encourage completion of the study.

With the consent of participants, Headspace provided us with objective user data. Clinicians provided information about consenting participants' number of counselling sessions, treatment-as-usual treatment modality, and the strength of their relationship with the client/participant. All outcome measures are presented in detail in the measures section.

Follow up qualitative studies with clinicians (debriefing focus groups) and participants (online or phone-based interviews) were planned for the end of the trial. These studies would have allowed participants to provide feedback on the implementation of mobile mindfulness within the counselling service as well as to gain rich qualitative data on user experiences. But, due to changes in service provision at the counselling service and researcher availability at the end of the trial, I deemed these follow up qualitative studies to no longer be appropriate nor feasible. Consequently, these planned qualitative studies were abandoned.

4.2.2. Sample size

Following discussion with the Principal Clinical Advisor (Dr. Tess Patterson, a clinical psychologist) and Andrew Gray (School of Medicine biostatistician), we considered a 5-point change in K10 to represent a clinically interesting difference, the equivalent of a 0.5 unit change on each of the 10 items or approximately 0.5 of a standard deviation. This rate of change was consistent with research suggesting that people are unable to discriminate between changes in health-related quality of life when those changes are smaller than 0.5 SD (Norman et al., 2003). A 0.5 or greater unit change should therefore be clinically meaningful for participants.

In order to provide 80% power to detect such a difference in change scores between any two arms of the study using a two-sided test at the 0.0167 level (i.e., conservatively allowing for a Bonferroni adjustment over the three post-hoc comparisons) and based on an expected SD of 8[34] to 9 (as indicated in Study 1a), a n = 56/arm would be required. Allowing for approximately 50%

[34] Personal communication with Prof. Sunny Collings and Dr. James Stanley (May 6, 2016). Collings and Stanley conducted semantically similar studies of this nature in similar study populations e.g., (Collings et al., 2012)

dropout/unusable data[35], I aimed to recruit a representative sample of 360 (or *n* = 120 per group) Dunedin-based students from the University of Otago who *we* considered distressed as indicated by opting in to the counselling service at Student Health Services for a variety of reasons such as depression, stress, and anxiety. The Director of Student Health Services, Dr. Kim Ma'ia'i (an advisor on this project), indicated this number would be feasible[36]. Participants would be recruited for a period of up to 18 months.

4.2.3. Participants

Participants were 86 university students (M=21.15 years, SD=3.87 years; 83.7% women, 14.0% men, 2.3% other/unsure) who were recruited through Student Health Services – Counselling Service by their clinicians at the University of Otago, Dunedin, New Zealand. Participants were largely of New Zealand European/Pākehā descent (77.9%; 9.3% Māori, 3.5% Pasifika; 5.8% Chinese; 3.5% Indian; 10.5% other) which generally reflected the wider university community. Students were predominantly undergraduate (*n* =64, 89.5%) and living in a flatting situation (*n* = 49; 57.0%). Baseline demographic characteristics did not differ by condition (all *ps* > .124; further demographic detail available in Supplementary Table 4.2.). See Figure 4.1. for CONSORT diagram demonstrating the flow of participants through each stage of the study.

To be eligible for this study, participants had to be at least part-time University of Otago students, and own a smartphone (roughly 97% of student body; Flett et al., 2015). As this study aimed to recruit participants who were broadly defined as distressed (consistent with pragmatic research trial design; Zwarenstein et al., 2008), all eligible participants were invited to participate

[35] This inflated estimation is consistent with and overshoots the 31% weighted average dropout rate in internet-based treatments for psychological disorders (that corrected for sample size; Melville et al., 2010).

[36] Director of Student Health Services, Dr. Ma'ia'i informed me that 277 students attended a counselling triage session between 11 July and 30 August 2016. Including only weekdays, this is an average of 7.5 students per day. Following consultation with the clinicians about their estimates of mindfulness as a suitable addition to treatment as usual, we estimated that at least two-thirds of new clients would be eligible and mindfulness would be an appropriate adjunct to treatment-as-usual. N.B., Some students who attend a counselling triage session do not go on to receive formal counselling but this high number suggested our recruitment aim was feasible. Further, retrospective projections using the counselling data requested by the New Zealand Student Unions' Associations (7.65% of enrolled students across all Aotearoa New Zealand universities used counselling services in 2017; (Smith, 2018) and University of Otago population statistics (2017, 18,457 equivalent full time students; https://www.otago.ac.nz/about/quickstats.html), suggests that approximately 1400 students would have used the counselling service in 2017.

by their Student Health Services Counselling clinician. Clinicians only invited clients whom they deemed to need further assistance through the Counselling Service. To maintain their professional autonomy, potential participants were only approached about the study if the clinician deemed mindfulness to be appropriate for their client (maintaining professional autonomy is consistent with factors that improve recruitment; Fletcher, Gheorghe, Moore, Wilson, & Damery, 2012). During consultation clinician's (rightly) maintained that not every therapy is the right therapy for every individual. In order to maintain their professional autonomy, it was important to the clinicians that they retained the authority to decide which therapies it was appropriate to offer their clients, and thus if they did not think that mindfulness was right for a client, they did not invite them to participate. Moreover, consultation with clinicians and the Director of Student Health Services determined that those with pre-existent or prodromal psychotic illnesses, including schizophrenia, psychosis, bipolar disorder; high and imminent risk of suicide, or post-traumatic stress disorder were not eligible to participate in the present study.

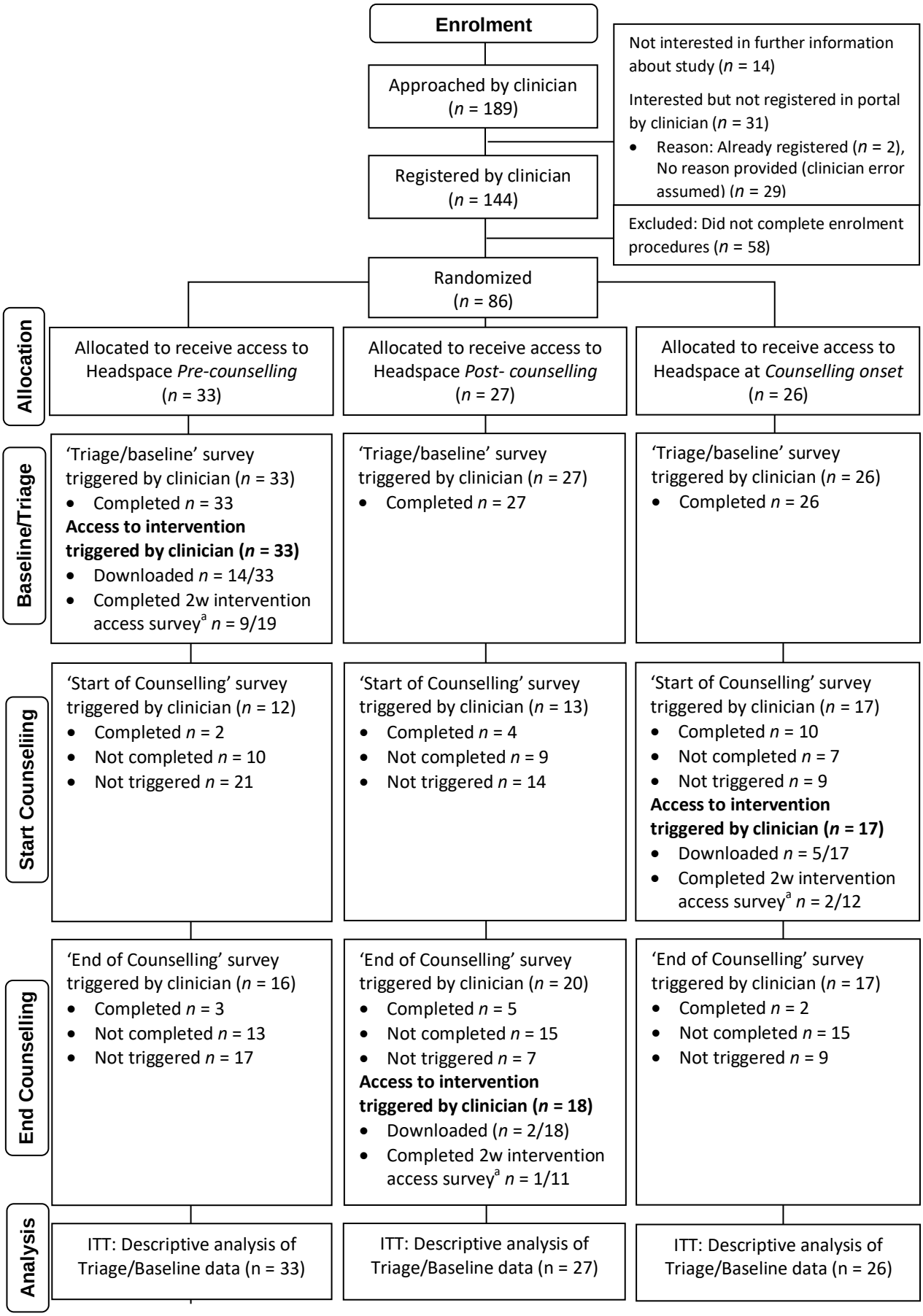

Figure 4.1. **CONSORT diagram of study participation.** ***a = Two-week intervention access surveys were abandoned on 12th April 2017 to reduce participant burden.***

4.2.4. Procedure

Participants were identified by, and provided initial consent (paper) to their clinician. Clinicians 'registered the interest' of clients in the study on the study portal. The study portal automatically sent clients a brief friendly automated email from the PI (Dr. Tess Patterson) with a link to online informed consent, and a baseline demographic and psychological outcomes survey. On the basis of this survey and provision of consent, participants were randomised (with stratification based on gender and ethnicity provided in Survey 1) into one of three conditions by the study portal: Mobile Mindfulness beginning before formal treatment (in the interim between initial assessment and beginning of treatment), Mobile Mindfulness beginning during treatment-as-usual, or waitlist control with Mobile Mindfulness following treatment. If they were randomised to 'Mobile Mindfulness beginning before formal treatment' then the portal automatically sent them an email about downloading and using Headspace.

Participants then underwent several study components: initial survey session following initial consult, app download and follow up survey, survey at onset of treatment, and survey at completion of treatment. An additional survey was initially sent out to participants two weeks after receiving access to Headspace. These surveys were abandoned on 12/04/2017 (as approved by the Health and Disability Ethics Committee [16/NTB/105/AM01) to reduce participant burden and to encourage completion of the study. Given that each individual had a different treatment duration (minimum = 1 treatment session; maximum = 6 treatment sessions) surveys were triggered by clinicians at the start and end of their counselling treatment. A brief final survey was sent to participants at the end of the academic year to check in on them. This procedure is illustrated in Figure 4.2.

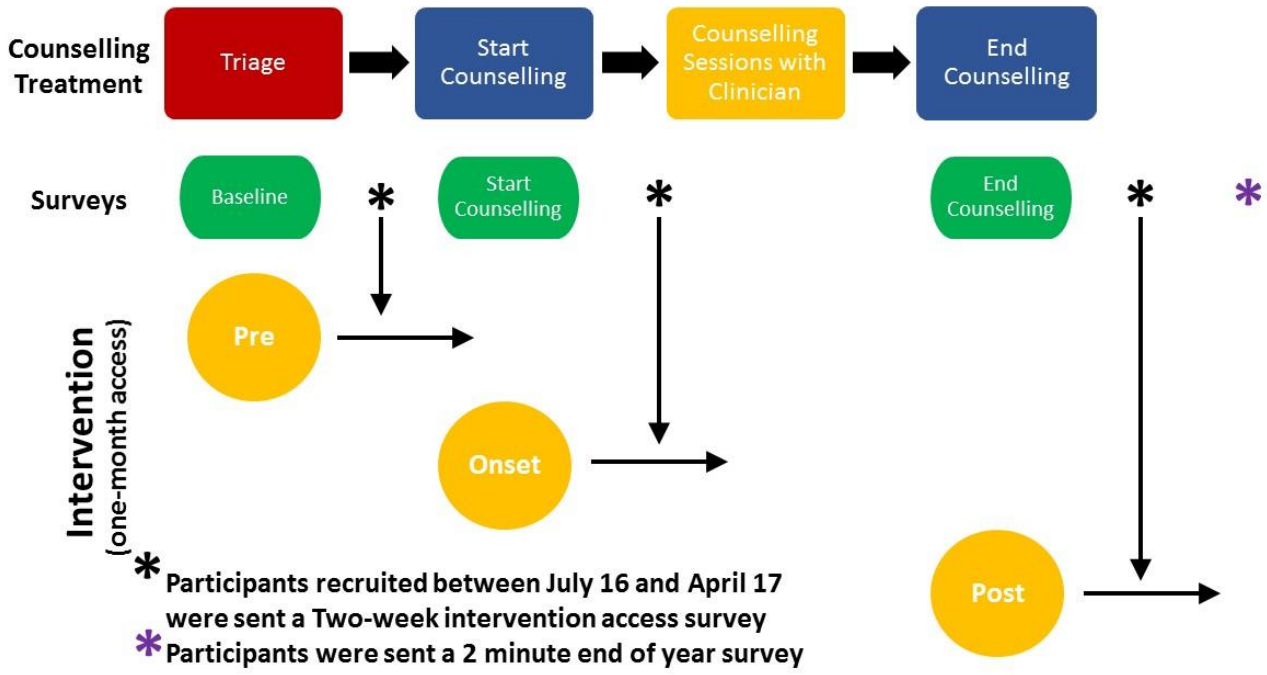

Figure 4.2. **Visual study design for "Mobile Mindfulness Meditation as an adjunct to treatment-as-usual in Student Health Services users: A randomised control trial".**

4.2.5. Application and materials

Headspace

As previously described in this thesis, Headspace is a smartphone application that offers hundreds of hours of guided and unguided mindfulness meditations delivered by Andy Puddicombe (a novice monk in the Theravada Tradition and fully ordained Tibetan Buddhist monk in the Karma Kagyu Lineage; Puddicombe, 2017). Participants were recommended to use the app at least once a day but were not required to do so. Participants were recommended to complete the compulsory Foundation 1 series first and then Foundation 2 and Foundation 3 (two introductory series of meditations following from the compulsory Foundation 1 series) before proceeding to other series in the app. See Supplement 4.3. for a full list of email communications with participants in this study, including instructions for downloading and using the app.

Surveys and Survey Website

Each participant received personalised counselling, specific to their needs (e.g., anywhere from 1 to 6 counselling sessions). To standardise the survey time points, surveys were triggered by their clinicians using the study website. Each clinician had a unique login to access the survey website. Clinicians inputted clients' student email addresses at the completion of the triage, first, and final consultations. If the client is enrolled in the study, the clinician could trigger the appropriate survey to be automatically sent to the participant's student email address. See Figures 4.3. and 4.4. for examples of the Clinician end study website using mock participants.

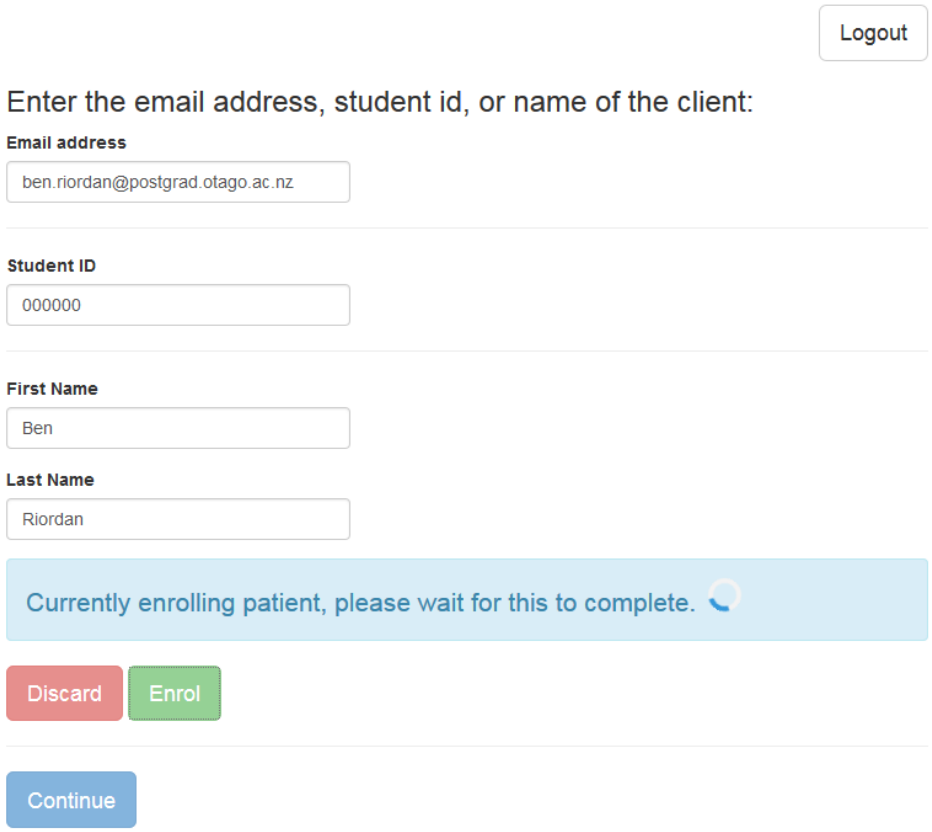

Figure 4.3. **Registering a client as 'interested in receiving more information'.**

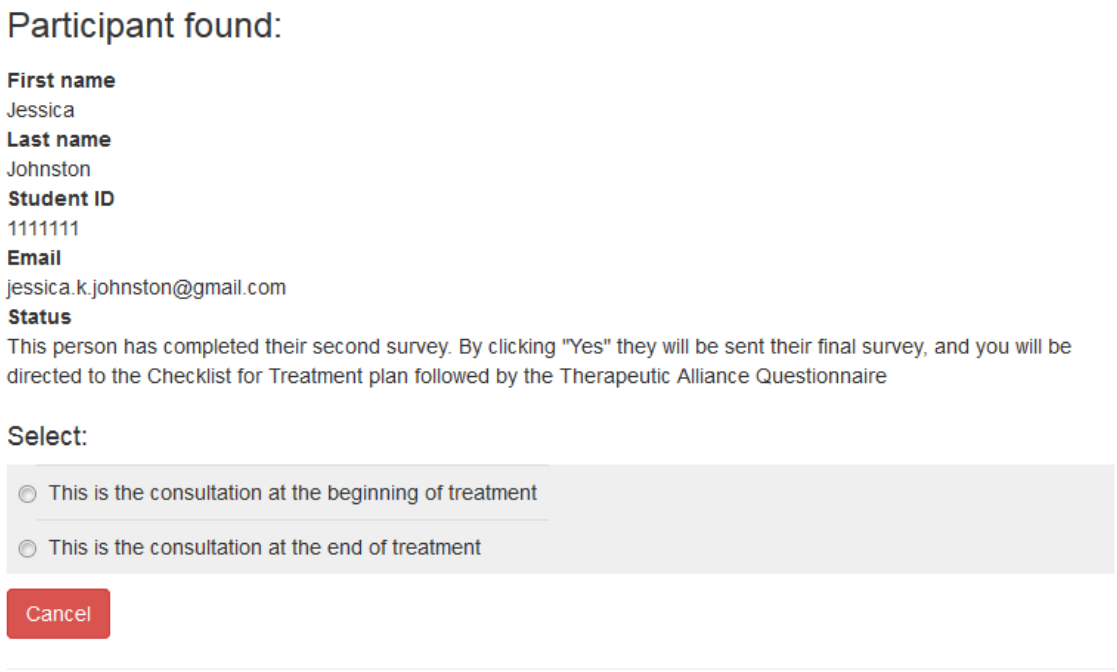

Figure 4.4. **Registering a client as finished treatment.**

Clinicians used the study portal to record a broad categorization of issues experienced by the client, details about their client's treatment, and their therapeutic alliance with the client. These measures are described in the measures section. If the client was ultimately not enrolled in the study, this information was not recorded. The study portal allowed clinicians to largely remain blinded to participants' condition in the study; however, as part of their treatment, participants may have chosen to discuss their participation in the study so I cannot be certain that they remained blinded.

Researcher Contact with Participants

During the various stages of the trial (e.g., expression of interest, start of treatment at counselling service), automated brief, friendly and informative emails were sent to participants from the Principal Clinical Advisor (Dr. Tess Patterson, supervisor and clinical research advisor). Although automated, participants were able to respond directly to the Dr. Patterson who was available to troubleshoot and answer questions about the study. The automated emails are available in Supplement 4.3. alongside an outline of the study timeline (Figure 4.2. presented earlier).

4.2.6. Measures

Where measures have been used previously, see earlier discussions of the measures for extensive detail (section: 3.1.4.). A number of psychological outcomes were selected in order to demonstrate whether a broad range of clinically-relevant and clinically-significant changes occurred across the spectrum of mental health. Changes in these outcomes were deemed relevant by the researchers and the clinicians. Measures were collected at all time points unless otherwise specified.

Demographics

In the baseline survey, participants provided basic demographic characteristics including age, gender (free text), ethnicity (New Zealand European/Pākeha, Māori, Samoan, Cook Island Māori, Tongan, Niuean, Chinese, Indian, Other – free text; participants were able to identify with more than one ethnic group), student status (part-time, full-time), and accommodation (residential college, flatting, parental home, in a home you own, boarding, in a studio room, other [free text]).

Distress

Distress was assessed using the 10-item Kessler Psychological Distress Scale (K10; Kessler et al., 2003) with an additional five questions that are often used to assess functioning and related factors (four functioning items in the K10+; LM [last month] plus one question to assess how often compared to usual the K10 feelings occurred; Australian Mental Health Outcomes and Classification Network, n.d.). The K10 (and the K10+) is a global measure of non-specific psychological distress that was designed to be sensitive to clinically-significant thresholds in order to differentiate between cases of serious mental illness (SMI) and non-cases. In the K10, participants rate the frequency of 10 experiences over the last month (e.g., felt so depressed that nothing could cheer you up) using a Likert scale from 1 [All of the time] to 5 [None of the time]. Responses were reverse scored. Summed scores range from 10-50 with higher scores indicating greater psychological distress. The additional items (i.e., +LM) are used independently to determine functional impairment. More specifically, these items assess the individual's ability to

function, how typical their K10 experiences are, and the extent to which these experiences resulted in professional help-seeking. Categorisations of K10 scores are situation and purpose dependent (i.e., different cut-offs are appropriate in different settings e.g., in primary healthcare to monitor distress vs. in specialist mental health services for those in specialist care to monitor distress vs. in a population survey to describe global distress; (Australian Bureau of Statistics, n.d.). While there are several recommendations for meaningful cut off points (Australian Bureau of Statistics, n.d.) here I use the following scoring categories provided by the Australian Bureau of Statistics and the Clinical Research Unit for Anxiety and Depression (CRUfAD) to interpret the scores when patients are already in specialist care. Scores are typically interpreted as follows (Australian Bureau of Statistics, n.d.):

> 10-19: The score indicates that the client or patient may currently not be experiencing significant feelings of distress.
>
> 20-24: The client or patient may be experiencing mild levels of distress consistent with a diagnosis of a mild depression and/or anxiety disorder.
>
> 25-29: The client or patient may be experiencing moderate levels of distress consistent with a diagnosis of a moderate depression and/or anxiety disorder.
>
> 30-50: The client or patient may be experiencing severe levels of distress consistent with a diagnosis of a severe depression and/or anxiety disorder.

An additional classification that is useful to describe the risk of transition to serious mental illness (K10 scores 30+), was described in Stallman (2010). Stallman maintained that scores between 16-29 (described as indicating probable mild-moderate mental illness) are also important because previous research indicates that mild-moderate mental illness is a strong risk factor of transition to serious mental illness (with scores 30+ described as indicating probable serious mental illness in Stallman, 2010; supporting evidence in Kessler et al., 2003). However, in keeping with research by the Health Promotion Agency Te Hiringa Hauora, I will use the term distress and psychological distress as the expressed preference of those with lived experiences (Kvalsvig, 2018) rather than terms relating to diagnosis of illness or mental illness. The K10 scale has high internal consistency (baseline α .83, respectively, similar to α .93; Kessler et al., 2002). Distress,

as measured by the K10, was the pre-registered primary outcome in this study (ANZCTR: #370690).

Depression

Unlike in Study 1, here depression severity was assessed using the 21-item Beck Depression Inventory II (BDI-II: (A. T. Beck, Steer, & Brown, 1996), a widely used measure of depression severity in *clinical* and research settings. Participants selected which of four statements best represented their current experiences for 21 experiences (e.g., 'Sadness' "I do not feel sad", "I feel sad much of the time", "I am sad all the time", "I am so sad or unhappy that I can't stand it"). The statements were scored from 0-3 with higher scores indicating increasing severity for the symptom of depression. Two items had seven options to indicate either an increase or decrease of appetite and sleep. Summed scores range from 0 to 63 with higher scores indicating more severe depressive symptoms. Scores are typically interpreted as follows:

0–13: minimal depression
14–19: mild depression
20–28: moderate depression
29–63: severe depression

This scale has high internal consistency (baseline α .91 respectively, similar to α .89; Whisman, Perez, & Ramel, 2000).

Anxiety

Unlike in Study 1, here anxiety was measured using the 21-item Beck Anxiety Inventory (BAI: Beck, Brown, Epstein, & Steer, 1988), a widely used measure of anxiety symptoms in *clinical* and research settings. Participants rated how often they were bothered by a particular feeling over the past month (e.g., Numbness or tingling, fear of worst happening) using a Likert scale from 0 [Not at all] to 3 [Severely]. Summed scores range from 0 to 63 with higher scores indicating more severe anxiety symptoms. Scores are typically interpreted as follows:

0–7: Minimal level of anxiety
8–15: Mild level of anxiety
16–25: Moderate level of anxiety

26–63: Severe level of anxiety

This scale has high internal consistency (baseline α .91 respectively, similar to α .94; Fydrich, Dowdall, & Chambless, 1992) and good test-retest reliability (Fydrich et al., 1992).

Stress

As in Study 1, perceived stress was assessed using the 10-item Perceived Stress Scale (PSS; Cohen, 1988). Summed scores range from 0–40, with higher scores indicating greater perceived stress. This scale has high internal consistency (baseline α .81) and acceptable convergent and divergent validity (Roberti, Harrington, & Storch, 2006).

Resilience

As in Study 1, resilience was assessed using the 6-item Brief Resilience Scale (Smith et al., 2008), a measure of the ability to bounce back or recover from stress. Averaged scores range from 1.00–5.00, with higher scores indicating greater resilience. Scores are typically interpreted as follows (B. W. Smith et al., 2013):

1.00-2.99: Low resilience
3.00-4.30: Normal resilience
4.31-5.00: High resilience

This scale has high internal consistency (baseline α .79 respectively, similar to αs .80 to .91 in Smith et al., 2008), good test-retest reliability and acceptably convergent and divergent validity (Smith et al., 2008).

Mindfulness

As in Study 1, mindfulness was assessed using the 12-item Cognitive Affective Mindfulness Scale – Revised (Feldman et al., 2006), a scale consisting of several facets of mindfulness. Summed scores range from 12 – 48, with higher scores indicating a greater level of the mindfulness facets: attention, present focus, awareness, and acceptance. This scale has acceptable internal consistency (baseline α .75 respectively, similar to αs .74 and .77 in Feldman et al., 2007) and acceptable convergent and discriminant validity (Feldman et al., 2007).

Flourishing

As in Study 1, flourishing was assessed using the 8-item Flourishing Scale (Diener et al., 2010), a measure of perceived achievement in areas such as relationships, self-esteem, purpose, and optimism that is commonly used as a proxy for psychological well-being. Summed scores range from 8 – 56, with higher scores indicating greater well-being. This scale has high internal consistency (baseline α .84 respectively, similar to α .87 in Diener et al., 2010, and .91 and .81 in Hone et al., 2014), good test-retest reliability (Diener et al., 2010) and adequate convergent and divergent validity (Hone et al., 2014).

Credibility and Expectancy

Credibility and treatment expectations were assessed using the 6-item Credibility and Expectancy Questionnaire (Devilly & Borkovec, 2000). Participants rated how credible they thought the mobile mindfulness was (e.g., How logical does mobile mindfulness seem?) using a Likert scale ranging from 1 [Not at all] to 9 [Very]. Baseline scores indicate perceived credibility and expectancy.

Therapeutic Alliance

Therapeutic alliance was measured in the Post-counselling survey using the 12-item Working Alliance Inventory – Short Revised and Working Alliance Inventory – Short Revised Therapist (WAI-SR and WAI-SRT: Hatcher & Gillaspy, 2006), a set of combined measures used to assess elements of the relationship between the participant and their treating clinician (e.g., agreement about treatment goals, agreement about treatment tasks, and quality of the interpersonal relationship). Participants and clinicians rated statements about their experience in counselling therapy (e.g., Participant: 'What I am doing in therapy gives me new ways of looking at my problem') on a Likert scale of 1 [Seldom] to 5 [Always]. Items were reverse scored where necessary and summed to create an overall score ranging from 12 to 60 (participants) and 10 to 50 (clinicians) with higher scores indicating a stronger client-therapist alliance.

App Adherence

As part of the information and consent process, participants agreed to allow Headspace to provide researchers with user data. For each participant, I was provided with the date and time of

each app use session, session duration (in minutes), session type (which content in Headspace they used), and status (completed vs. uncompleted). I analysed these metrics to determine the number of meditation sessions they completed, the amount of time spent meditating, and the types of meditation content they were accessing.

Clinician Measures

Clinicians recorded the broad primary care classification for why the client was accessing the counselling service (e.g., academic, acute reaction to stress, etc.). When clinicians logged a transition in their clients treatment (i.e., triage, start or end of treatment), the study portal also asked what therapy modalities (e.g., Cognitive Behavioural Therapy) they used during that session (at triage and start of treatment) or across the treatment sessions (end of treatment). All primary care and treatment classifications are provided in Tables 4.2. and 4.3. At the end of treatment, clinicians reported their therapeutic alliance with their client using the 10-item Working Alliance Inventory – Short Revised Therapist (WAI-SRT: Hatcher & Gillaspy, 2006) described above.

4.2.7. Other considerations

Risk to Participants

Mindfulness meditation is a common course of therapy for individuals with mood disorders such as major depressive disorder and anxiety disorders (Davis & Hayes, 2011). For example, in the UK, MBCT is recommended by the National Health Service (NHS) as a treatment option for depression relapse prevention (National Institute of Health and Clinical Excellence, 2009). A Mindfulness All-Party Parliamentary Group review recommended that MBCT should be available through the NHS for those at risk of recurrent depression and for those with long-term physical health conditions (The Mindfulness Initiative, 2015). As discussed earlier in Chapter 1 (section 1.3.6.) there is some evidence that mindfulness meditation can have negative or adverse effects in some people. Although the adverse effects research is sparse, eminent mindfulness researchers Baer and Kuyken (2016) have suggested that novice meditators typically should not experience the aforementioned adverse effects, especially when they are only meditating at an

introductory level for 10-20 minutes per day. Although there were no serious risks identified for brief introductory mindfulness-based practices when I first designed this study, to minimise risk to participants in this study, I wrote and adhered to a trial safety protocol. Most pertinent to the safety protocol, if individuals experienced momentary increased distress by taking part in this project and using the mindfulness app, they were advised to cease mobile mindfulness meditation. If the distress was prolonged or marked or they were concerned, they were informed to contact Student Health Services' Dr. Kim Ma'ia'i (advisor on this thesis and Director of Student Health Services at the time of conducting this study) or Dr. Jubilee Rajiah (clinical psychiatrist). Dr. Ma'ia'i and Dr. Rajiah offered to conduct an over the phone clinical assessment in order to determine the appropriate response to the participant's experience (see trial safety protocol in Supplement 4.4. for further details); no participants used this assessment.

Participant Burden

To reduce participant burden, I designed the study so that participants would have all surveys and reminders delivered to their email. To further reduce burden, I only measured the most clinically important outcomes. As a pragmatic trial, I reassessed burden at several stages throughout data collection. For example, given the low participant retention, I removed several survey points (namely the two-week access survey) to reduce participant burden.

Clinician Burden

A number of changes to usual clinic practice were put in place to implement the intervention in order to reduce burden for the clinicians. There were a number of iterative changes to the study design intended to reduce burden on the clinicians; all changes were made in response to consultation with the clinicians. For example, early in the study design phase when I consulted with clinicians across multiple group meetings, the clinicians indicated that unless they had documented consent, they would be uncomfortable providing the contact details of clients who were interested in hearing more about the study through the portal. To overcome this concern, we used a 'double consenting' process. In the initial consent, participants provided consent for their clinician to share their contact details with the researchers (who would then provide them with

greater detail about the study). Initial consent also provided consent for the clinician to provide general information about a *consenting* participant's treatment given (i.e., number of sessions, treatment modality), therapeutic alliance between client and clinician, and a broad classification as to why the participant was seeking help through the Counselling Service (e.g., depressive symptoms, anxiety, grief, relationship issues, family issues). In a separate online consent, participants provided consent to take part in the research trial. Information provided by the clinician about a client was only recorded if the client provided online consent to take part in the trial.

Following feedback from clinicians that it was hard to remember to register that their clients had started or ended counselling treatment, clinicians received an automated email on Wednesday morning and Friday afternoon reminding them of their clients who were still enrolled in the study (and the stage that client was in i.e., interim between triage and beginning treatment, undergoing treatment, treatment completed). Clinicians also requested that the portal allow them to unenroll a participant from their automated email if they had been transferred to a different treating clinician.

To facilitate the 'broaching of the topic' of the research study at the end of a triage session, clinicians suggested it would be useful to provide an abridged information sheet for participants to read prior to entering their appointment. In usual practice, new clients are given a clip board with paperwork to fill out prior to entering their appointment. Here, the administrative staff provided a brief one-page information sheet about the study to participants. This helped to 'break the ice' and also reduced the amount of time clinicians needed to dedicate to the study in their contact time with clients.

Following feedback from clinicians and low participant retention, I began to collect participants' mobile phone numbers so that they could be texted using a commercial texting platform to remind them of survey completion, however, only 3 participants provided these details and this practice was disbanded after one month of inactive use.

4.2.8. Data analyses plan

The following data analyses plan was registered with ANZCTR following repeated statistical consultation with Mr. Andrew Gray (Biostatistician, Dunedin School of Medicine, University of Otago).

Primary analysis. Our primary analysis was intended to address the modified intention-to-treat question about treatment effectiveness (using all available data) using the primary psychological outcome variable 'psychological distress' (as measured by K10, Kessler et al., 2003) at the end of Counselling Service treatment with a clinician (End of counselling; See Figure 4.2. for study timeline). I intended to conduct mixed model regression analyses, with treatment included as a fixed effect and participant as a random effect (to accommodate repeated measures). Distress (outcome) and end of Counselling Service treatment with clinician (time) was intended to be my primary analysis outcome and time point. I recognised that I may have issues with missing data (not at random or completely at random), thus I intended to use multiple imputation with chained equations to account for the missing data.

Secondary analyses. All remaining statistical analyses were intended to be secondary and subsequently *exploratory* analyses, e.g., a per protocol efficacy analysis to examine adherence (use of app as indicated by user data supplied by Headspace in order to examine 'dose' effects), therapeutic alliance, and treatment modality (from the Counselling Service) as mediating factors in psychological distress. Further secondary analyses were to examine potential mediating factors in relation to other psychological outcomes including depression, stress, anxiety, mindfulness, flourishing, and resilience. Finally, analyses were to examine whether gender or demographic factors moderate psychological distress and other psychological outcome variables. Analyses were to test for differences between both the intervention groups (Mobile Mindfulness before and during Treatment-as-usual) and the waitlist control group (Mobile Mindfulness after Treatment-as-usual) on changes in psychological health at each stage of treatment (initial consult, onset of treatment, end of treatment). Overall, the goal was to understand whether our intervention results in increased mindfulness practice and whether that increase in mindfulness practice translated into

noticeable improvements in psychological well-being (primarily lower psychological distress; secondarily all other psychological outcome variables: depression, stress, anxiety, mindfulness, flourishing, and resilience), and whether such changes in well-being were mediated by psychological expectancies or therapeutic alliance with their clinician, or moderated by demographic factors such as gender or ethnicity.

4.2.9. Revised data analyses plan

Due to low recruitment (*n* = 86; 51.1% of minimum *N* recruited) and grossly high survey attrition (*n* completed 2+ surveys = 29; survey attrition = approximately 88% at all follow up points) it was deemed inappropriate to conduct the planned analyses (that is, there were <50% missing data across the planned analyses; consistent with Manly & Wells, 2015). Thus, instead I present basic descriptive statistics of baseline mental health characteristics, reasons for attending counselling, therapy used by clinicians, app use data, and a single analysis of the effect of exposure to the intervention on the primary outcome, distress. I also present recruitment and participant retention statistics.

Missing Data. As expected, within the available data there was a small but acceptable amount of missing data (95.0% of variables have at least one missing data point; 60.7% of cases have missing data; 8.1% missing data across the available dataset). For instance, several coding errors were not identified during piloting because the back end of the study portal was written in a coding language by the department's programmer in a coding language that I am unfamiliar with. Thus, for several early participants I am missing (at random) some demographic variables (age, ethnicity, accommodation, and year at university; missing values by variable ranged from 2.3-15.1% across demographic variables) and Beck Depression items 6-21 (missing values 49.2% across items 6-21). In addition, there were several one-off missing data points across the remaining variables (15 missing data points total, which is 3.3-6.6% missing values over the range of variables) due to item non-response (participants missed a single question of a scale). Item non-response missingness was not significantly correlated with any other variable. Rates of missingness did not significantly differ across conditions (all *ps* < .290). Where participants

completed surveys, I have addressed the problem of acceptable missing data using SPSS 23's multiple imputation with chained equations to generate 20 imputed datasets (in line with Graham, Olchowski, & Gilreath, 2007; White, Royston, & Wood, 2011, recommendations). Demographic imputations were generated separately from the final data set so as to not impute multiple demographic data for a single participant. Demographic imputations required higher iterations than the default in order to generate imputed values that converged with the categorical 0/1 parameters for 'Ethnicity = New Zealand European/ Pākehā. All remaining data were generated using all remaining variables (i.e., all variables that make up the outcome variables outlined previously). Analyses were pooled using SPSS 23's naïve/univariate combination. Imputed values were used to create overall outcome variables (e.g., Distress from K10-1 to K10-10).

4.3. Results

The results are reported in three sections: In the first section, I report descriptive statistics on recruitment, retention, and survey completion rates. In the second section, I report the presenting characteristics and baseline mental health measures of recruited participants, and app use rates. In the third section, I report the effect of exposure to the intervention on distress using available data.

4.3.1. Recruitment, retention, and survey completion

During the 16-month recruitment period (July 2016 to October 2017), 189 clients were approached by clinicians. Over 90% of the clients who were approached about the study, expressed interest in receiving information from the researchers about the study (92.5%; n = 175). Over 80% of those who requested further information about the study were registered as 'interested' in the study portal by their clinician (82.3% registered; n = 144). Almost 60% of those who were sent information about the study were recruited as participants (59.7%; n = 86). Overall almost 50% of those who were approached by clinicians, were recruited as participants (47.1%; n = 86/189).

Clients approached vs clients registered: a complex study portal

As outlined earlier, I aimed to recruit 120/condition. At the outset of this project, that number seemed feasible[37], in hindsight, it was not. As demonstrated in Figure 4.5., the approach rate (indicated by the blue bars) fluctuated over the course of the year. Clinicians approached the most clients at beginning of the Semester 2 (July 2016) and at the beginning of Semester 1 (February/March 2017). This approach rate dropped off as the semester progressed and is likely due to clinician workload (informally reported by clinicians during our regular meetings). A spike in approach rates was expected for June 2017, however, at this stage the clinicians had just begun to undergo a Service Review which ultimately resulted in their positions being restructured.

The orange and yellow bars in Figure 4.5., represent the total number of clients registered as interested in receiving further information by their clinician; yellow representing clients who were not recruited to the study and orange representing recruited participants. If the recruitment system was sound, the combined orange and yellow bars should be equal to the dark blue bars. Registration rates did not match the approach rates at the beginning of the study. That is, in the first two months of the study, clinicians were approaching participants but not always registering them. Recruitment rates naturally dropped off over the year and built back up at the start of the following academic year (February/March 2017). At this stage, interest in participation was far lower, the proportion of participants who were not recruited (yellow) compared to those who were recruited (orange) was greater during this time. Interestingly, across several months, clients registering as interested in the portal was higher than the number that clinicians reported they approached; this may be due to a delay in registering some clients after their triage which meant their approach and registration fall on different months.

[37] On the basis of new client numbers provided by Student Health Services, I estimated that there would be approximately 7.5 new clients per day. Following consultation with the clinicians about their estimates of mindfulness as a suitable addition to treatment as usual, we estimated that at least two-thirds of new clients would be eligible (i.e., during the academic year we expected ~ n = 5/day or 25/week or 100/month between March and October – academic year). After considering several additional factors (for example, 1: some students who attend a counselling triage session do not go on to receive formal counselling, 2: counselling service use fluctuates and 3: not all new clients would be interested in taking part in the trial), we believed we would be able to recruit enough participants in 18 months (or 12 months including only the academic semesters' months).

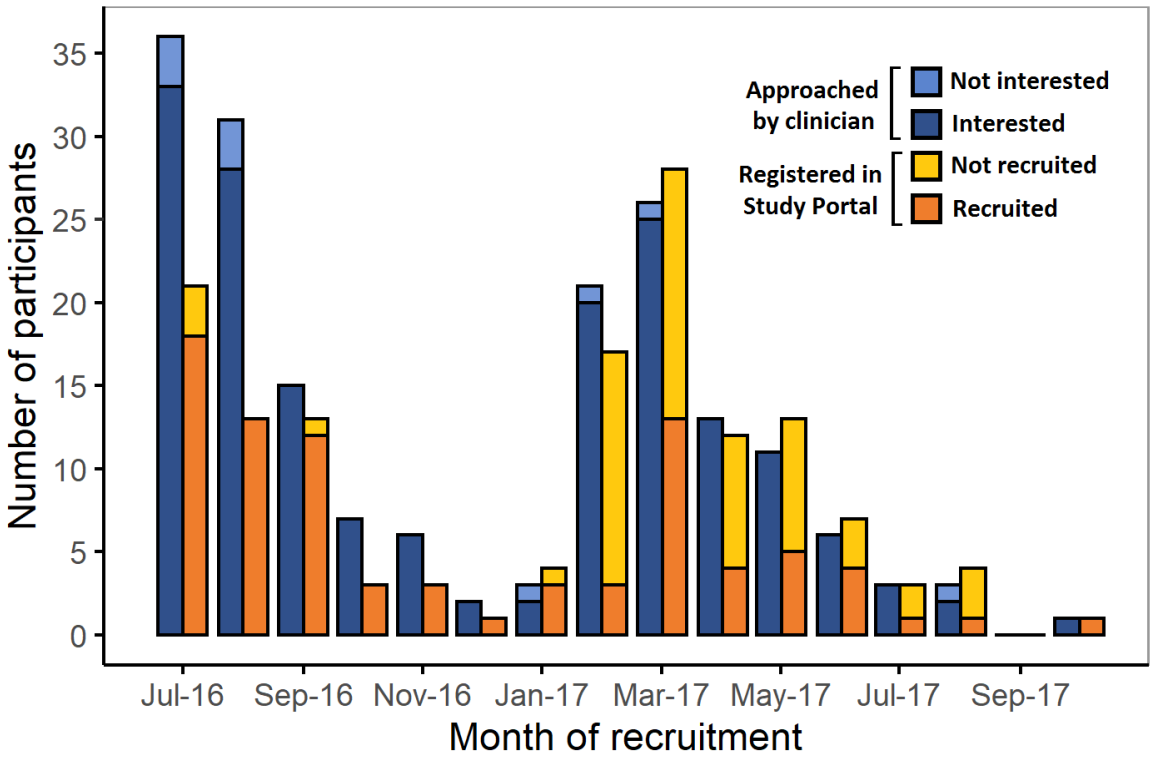

Figure 4.5. **Recruitment rate by month across the study period.**

Loss-to-follow up, survey completion and correlates

Of the 86 participants recruited to the study, only 29 participants (33.8% of overall sample) completed two or more surveys. The low survey completion rate was impacted by the complex context in which this intervention was conducted. That is, each participant had a different treatment timeline (i.e., some only had 1 session with a clinician, some had 6, and the time between sessions varied). Because of this variation in treatment timeline, surveys were tied to the start and end of counselling treatment. Given that the start and end of counselling varied by participant, I relied on the clinicians to report when their client started and ended counselling. These reports automatically initiated the survey to be sent to the participant. As demonstrated in the Table 4.1. (below), the loss-to-follow up (LTF) rate was approximately 50% at the start of counselling but lower at 38% at the end of counselling. Although some of this lost-to-follow up is likely to be genuine (i.e., clinicians reported that it was common for students to not return to

counselling despite having booked sessions), given that the rate of LTF for start of counselling is higher than the rate of LTF for end of counselling - some of the LTF was likely due to oversight (i.e., they were not registered as starting counselling when they should have been). In May 2017, the rates of LTF were of concern to the research team; we raised this concern with the ethics committee and monitored the situation.[38] Although rates of LTF were high in HS pre-counselling participants (approximately 65%) and low in HS during counselling participants (approximately 35%), they were not statistically different across conditions (**$X^2(2)=4.90$, $p = .086$). Despite the high LTF, there were no statistically significant differences in baseline mental health between registered as started or finished counselling as compared to those who did not (all *ps* < .152).

Of those who were retained in the study (i.e., not LTF), 38% completed the start of counselling survey (*n* = 16/42) and 19% completed the end of counselling survey (*n* = 10/53). There were no differences in survey completion rates between conditions when LTF rates were accounted for at the start of counselling ($X^2(2)=5.73$, $p = .057$), nor at the end of counselling ($X^2(2)=1.05$, $p = .591$). Likewise, no baseline demographic or mental health characteristic was correlated with survey completion (all *ps* <.100).

[38] Letter of update to the Health and Disability Ethics Committee #16/NTB/105 11/05/17

"In the process of conducting our monthly preliminary data analysis (for data management, recruitment tracking, and quality assurance), we noticed that participants who were given the opportunity to download the Headspace mobile application (app) prior to psychological treatment appeared to be less likely to attend their appointment with a clinician (9 out of 25 people returned for treatment) compared to those who were not given the opportunity to download the Headspace app prior to treatment (33 out of 43 returned for treatment). Although statistical analyses did not show a statistically significant difference in these numbers ($\chi(1) = 3.181$, $p = .204$), the trend has caught our attention. It is possible that the pattern could indicate greater self-efficacy in the participants receiving the app—in other words, using the app may have helped participants resolve the issues that were concerning to them. It is also possible, however, that the app might deter people otherwise assessed as needing psychological treatment. We cannot be sure of the pattern at this stage because of our low *n*.

Given that participants in the study were assessed as needing psychological treatment, and the Headspace app is being used as an adjunct to treatment not as a replacement to treatment, we will continue to monitor this trend and any unintended consequence of the study (e.g., participants not engaging in treatment with a clinician). If we obtain evidence that participants who have access to the Headspace app are less likely to engage in treatment with a clinician (i.e., chi-square with a $p < .05$), the researchers will immediately meet and consider the clinical implications of such a finding, ways to resolve the issue and/ or consider a halt to the study. Currently, we do not have evidence that this is the case and we will continue to collect data."

Table 4.1.

Proportion of participants lost-to-follow up due and survey completion (or attrition)

Condition	Timepoint Baseline/Triage	Start of counselling	End of counselling
Overall *N* = 86			
LTF	0	.51	.38
Survey attrition	0	.62	.81
Survey completion	1	.38	.19
HS Pre-counselling *n* = 33			
LTF	0	.64	.52
Survey attrition	0	.83	.81
Survey completion	1	.17	.19
HS Counselling onset *n* = 26			
LTF	0	.35	.35
Survey attrition	0	.41	.88
Survey completion	1	.59	.12
Headspace Post-counselling *n* = 27			
LTF	0	.52	.26
Survey attrition	0	.69	.75
Survey completion	1	.31	.25

Note. LTF = Proportion of participants lost-to-follow up (i.e., clinician did not register the participant as having started/ended counselling; these participants did not receive a survey).
Survey attrition = Proportion of participants registered that did not complete the survey (*n* registered but did not complete survey/*n* registered).
Survey completion = proportion of participants registered that did complete survey (*n* completed/ *n* registered).

4.3.2. Counselling service presenting and baseline mental health characteristics

As indicated in Table 4.2., participants presented to the counselling service for a wide range of reasons, with the most common reasons being anxiety (*n* = 54, 62.8% of the sample) and depressive symptoms (*n* = 46, 53.5% of the sample). The majority of participants presented for more than one reason (*n* = 72, 83.7% of the sample). Similarly, as indicated in Table 4.3., clinicians used a wide variety of therapies during the participant's treatment-as-usual. The most common modalities were psychoeducation (*n* = 63, 73.3%) followed by counselling in general (*n* = 42, 48.8%). Finally, clinicians reported that participants attended on average 2.92 (SD = 2.00) counselling sessions. Although the number of sessions did not differ by condition, receiving Headspace earlier was associated with approximately a .5 reduction in number of counselling sessions used by participants (HS Pre-counselling: *M* = 2.61, SD = 2.04; HS Counselling onset: *M* = 2.98, SD = 2.05; HS Post-counselling: *M* = 3.26, SD = 1.91; $F(2,82)=.78$, $p = .461$).

Table 4.2.

Reasons for attending counselling (as indicated by clinician) overall and by condition using complete case (per-protocol) data

	n	%
n	86	
Anxiety	54	62.8
Depressive symptoms	46	53.5
Academic	29	33.7
Acute reaction to stress	24	27.9
Family issues	21	24.4
Physical symptoms (i.e., somatic, sleep etc)	20	23.3
Relationships	20	23.3
Developmental/adjustment	15	17.4
Suicidal ideation	10	11.6
Other (not specified)	9	10.5
Grief	8	9.3
Traumatic events	6	7
Disordered eating/body image	5	5.8
Alcohol and other drug	3	3.5
Sexuality	0	0
Missing data	3	3.5

Note. Percentages total greater than 100% because participants may have presented with multiple reasons.

Table 4.3.

Therapy modalities used during treatment as usual (TAU) (as indicated by clinician) overall and by condition using complete case (per-protocol) data

	n	%
n	86	
Multiple therapies endorsed	64	74.4
Psychoeducation	63	73.3
Counselling (general)	42	48.8
Psychodynamic	32	37.2
CBT	14	16.3
Narrative therapy	10	11.6
Mindfulness exercises	8	9.3
Psychotherapy	6	6.9
App (mindfulness)	3	3.4
Mindfulness-based therapy	2	2.3
DBT	2	2.3
Psychoanalytic	2	2.3
Gestalt	1	1.2
App (online counselling)	1	1.2
ACT	0	0
Interpersonal psychotherapy	0	0
None specified	10	11.6

Note. Percentages total greater than 100% because clinicians may have used multiple therapies with their client.

As demonstrated in Table 4.4., there were no statistical differences in mental health characteristics between conditions at baseline (using per-protocol data and intention-to-treat data); thus, the randomization procedure used was successful. In this sample, average distress levels in this sample were high and indicate that the participants may be experiencing severe levels of distress consistent with a diagnosis of a severe depression and/or anxiety disorder. More specifically, 6% scored between 10-19 (n = 6, indicating they are unlikely to be experiencing significant distress), 8.4% scored between 20-24 (n = 7; indicating mild distress consistent with a diagnosis of mild depression or anxiety), 21.7% scored between 25-29 (n = 18; indicating moderate distress consistent with a diagnosis of moderate depression or anxiety), and 61.4% scored between 30-50 (n = 51; indicating severe distress consistent with a diagnosis of severe depression or anxiety; $n_{\text{missing data}}$ = 3; Australian Bureau of Statistics, n.d.). Using Stallman's (2010) additional categorisation, all participants' scores were either 16-29 (n = 32; 38.6%) or 30-50 (as above); indicating almost 40% of the sample was at heightened risk of transitioning to serious or severe distress (scores of 30+). Functional impairment (frequency

of distress and inability or reduced function as a result of distress, measured using the K10+, Kessler et al., 2002) was also high in this sample. On average, participants were unable to function at all for one week in the past month and reported reduced ability to function for 10 days in the past month. Consistent with other cut-offs, the average scores for this sample could be described as moderately depressed and anxious with low resilience.

Table 4.4.

Baseline mental health characteristics for per-protocol (complete cases) and intention-to-treat (pooled multiple imputation; 20 iterations) overall and by condition

Per-protocol data											
	Overall		HS Pre-counselling		HS Counselling onset		HS Post-counselling		One Way ANOVA		
	M	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*F*	*df*	*p*
Distress	31.25	6.58	31.34	7.18	30.54	5.99	31.88	6.58	.26	2, 80	.768
Distress frequency	5.55	1.26	5.52	1.06	5.50	1.27	5.65	1.50	.12	2, 80	.890
Days/30 unable to function	7.42	6.92	8.26	6.63	5.35	6.72	8.50	7.24	1.74	2, 80	.181
Days/30 of reduced function	10.24	6.93	10.31	6.83	10.12	7.50	10.27	6.74	.01	2, 81	.994
Distress-related Dr visits	2.06	1.08	1.91	.86	1.96	.96	2.35	1.38	1.36	2, 81	.263
Physical health as cause of distress	1.84	.97	1.75	.88	1.88	.88	1.92	1.16	.25	2, 80	.780
Depression[a]	26.88	12.01	26.56	15.05	24.77	7.68	29.67	11.06	.52	2, 40	.599
Anxiety	24.64	11.44	24.56	10.94	25.04	11.21	24.37	12.59	.02	2, 81	.977
Stress	26.78	5.62	26.72	6.71	26.75	4.61	26.89	5.22	.01	2, 80	.993
Resilience	2.38	.64	2.36	.69	2.37	.63	2.41	.61	.05	2, 81	.954
Flourishing	34.75	8.34	35.45	9.69	33.83	7.60	34.77	7.44	.25	2, 78	.779
Mindfulness	23.62	5.09	23.90	5.93	23.46	4.70	23.44	4.57	.07	2, 80	.928
Intention-to-treat											
	Overall		HS Pre-counselling		HS Counselling onset		HS Post-counselling		One Way ANOVA[b]		
	M	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*F*	*df*	*p*
Distress	31.33	7.44	31.34	7.14	30.54	5.99	32.09	6.41	.38	2, 83	.686
Distress frequency	5.48	1.36	5.37	1.29	5.50	1.27	5.60	1.53	.27	2, 83	.784
Days/30 unable to function	7.62	7.12	8.56	6.93	5.35	6.72	8.67	7.26	2.03	2, 83	.140
Days/30 of reduced function	10.42	7.09	10.50	7.05	10.12	7.50	10.61	6.70	.07	2, 83	.934
Distress-related Dr visits	2.08	1.12	1.93	.96	1.96	.96	2.38	1.44	1.46	2, 83	.273
Physical health as cause of distress	1.89	1.02	1.79	.94	1.91	.91	1.99	1.21	.34	2, 83	.723
Depression	26.25	9.05	26.90	11.35	24.83	6.23	26.84	8.27	.53	2, 83	.615
Anxiety	24.66	11.34	24.73	10.85	24.88	11.01	24.37	12.59	.02	2, 83	.984
Stress	26.79	5.57	26.60	6.67	26.93	4.49	26.89	5.22	.04	2, 83	.966
Resilience	2.39	.65	2.36	.68	2.37	.63	2.45	.64	.19	2, 83	.833
Flourishing	34.49	8.35	34.82	9.90	33.92	7.33	34.62	7.43	.10	2, 83	.906
Mindfulness	23.68	5.10	24.05	5.88	23.46	4.70	23.44	4.57	.14	2, 83	.869

Note. HS = Headspace; a: $n = 43$ due to coding error. b: In line with van Ginkel et al.'s (2019) recommendations for when combination rules are unavailable, for the ITT analyses I used an ad-hoc method to pool the ANOVA.

As demonstrated in Table 4.5., only one-third of participants enrolled in this study used the app at all. Specifically, only 21 of 68 participants (31%) ever accessed the app, leaving 46 people (69%) who never accessed their app even once. For the 21 people who did access the app (app users), on average, they meditated 10 times over the course of 16 days, approximately half of the available access period. App users primarily completed meditations that focussed on building mindfulness skill or reducing distress. There were no statistically significant differences between conditions in any app use variables, however, as demonstrated in the correlation matrix Table 4.6. those who accessed the app (n = 21 app users) were more mindful and less distressed, depressed, and stressed at baseline compared to those who did not use the app at all (n = 46). In post-hoc one-way ANOVAs, the differences between app-users and non-users in baseline mindfulness, distress, depression, and stress were all statistically significant (all p's <.024). This finding suggests that more distressed people were less likely to use the app.

Table 4.5.

Descriptive statistics of objective app use overall and by condition

	Overall			HS Pre-counselling			HS Counselling-onset			HS Post-counselling			One Way ANOVA (Chi Square)		
	N	*M* (SD)	Min-Max	*N*	*M* (SD)	Min-Max	*N*	*M* (SD)	Min-Max	*N*	*M* (SD)	Min-Max	$F(X^2)$	*df*	*p*
n randomised to receive app	86			33			26			27					
n sent app by portal[a]	68			33			17			18			14.19	2	<.001
n who used app	21			14			5			2			5.37	2	.068
n meditations completed	21	10.14 (8.95)	1-34	14	9.79 (7.82)	1-24	5	12.40 (13.13)	2-34	2	7.00 (8.49)	1-13	.272	2, 18	.765
Minutes meditated	21	98.76 (88.2)	10-326	14	94.86 (78.92)	10-250	5	121.20 (125.53)	20-326	2	70.00 (84.85)	10-130	.261	2, 18	.773
Duration of meditation practice in days[b]	21	16.05 (11.67)	0-30	14	16.79 (10.86)	0-29	5	15.80 (14.81)	0-30	2	11.50 (16.26)	0-23	.166	2, 18	.848
n Mindfulness skill-related meditations	21	9.10 (7.71)	1-30	14	8.71 (6.47)	1-24	5	11.40 (11.70)	2-30	2	6.00 (7.07)	1-11	.376	2, 18	.692
n Distress-related meditations	3	6.00 (6.93)	2-14	1	14.00 (na)	14-14	1	2.00 (na)	2-2	1	2.00 (na)	2-2	.	2, 0	
n Sleep-related meditations	4	1.25 (.05)	1-2	1	1.00 (na)	1-1	2	1.50 (.71)	1-2	1	1.00 (na)	1-1	.250	2, 1	.816

Notes. HS = Headspace a. Access to the intervention was initiated by clinicians registering their client's stage of counselling treatment. b. First day to last day. One Way ANOVA compares the three conditions (HS Pre-counseling, HS Counselling-onset, HS Post-counselling).

Table 4.6.

Correlation matrix of app use characteristics by demographic and baseline mental health characteristics for complete cases

		Meditated	*n* meditation sessions	Minutes Meditated	Age	Gender (female)	Ethnicity (NZ European/ Pākehā	K10 Distress	Depression	Anxiety	Stress	Resilience	Flourishing	Mindfulness
Meditated[a]	Pearson r	1	.b	.b	.169	-.068	.135	-.303*	-.620**	-.179	-.246*	.117	.025	.265*
	Sig.		.000	.000	.204	.584	.278	.013	.000	.150	.046	.344	.846	.031
	N	68	21	21	58	68	67	66	34	66	66	67	64	66
n meditation sessions	Pearson r		1	.989**	.473*	.017	-.133	-.104	.453	.000	.077	.219	.230	-.028
	Sig.			.000	.048	.941	.577	.653	.260	1.000	.741	.340	.329	.906
	N		21	21	18	21	20	21	8	21	21	21	20	20
Minutes Meditated	Pearson r			1	.529*	.017	-.145	-.073	.471	.018	.112	.180	.194	-.091
	Sig.				.024	.943	.541	.753	.239	.939	.630	.435	.413	.703
	N			21	18	21	20	21	8	21	21	21	20	20

**. Correlation is significant at the 0.01 level (2-tailed). *. Correlation is significant at the 0.05 level (2-tailed). a = This a dummy variable for whether they used the app one or more times (*n*= 21) versus zero times (*n*=47). b = Cannot be computed because meditated is constant.

4.3.3. Effect of exposure to the intervention on distress

Using the limited available data, change scores in the primary outcome, distress, were created[39] and are presented in Figure 4.6. When selecting only those who had been sent access to Headspace (recall that access to the intervention was initiated by clinicians registering their client's stage of counselling treatment, if the stage of treatment was not registered, access was not triggered) as there was no statistically significant difference between change scores as a function of condition (HS pre-counselling: n = 10, M = .50, SD = 2.88; HS counselling-onset: n = 3, M = -5.00 SD = 3.61; HS post-counselling n = 3, M = -9.00, SD = 13.89; $F(2,13) = 3.14$, p = .077). This analysis should be interpreted with caution given the low n.

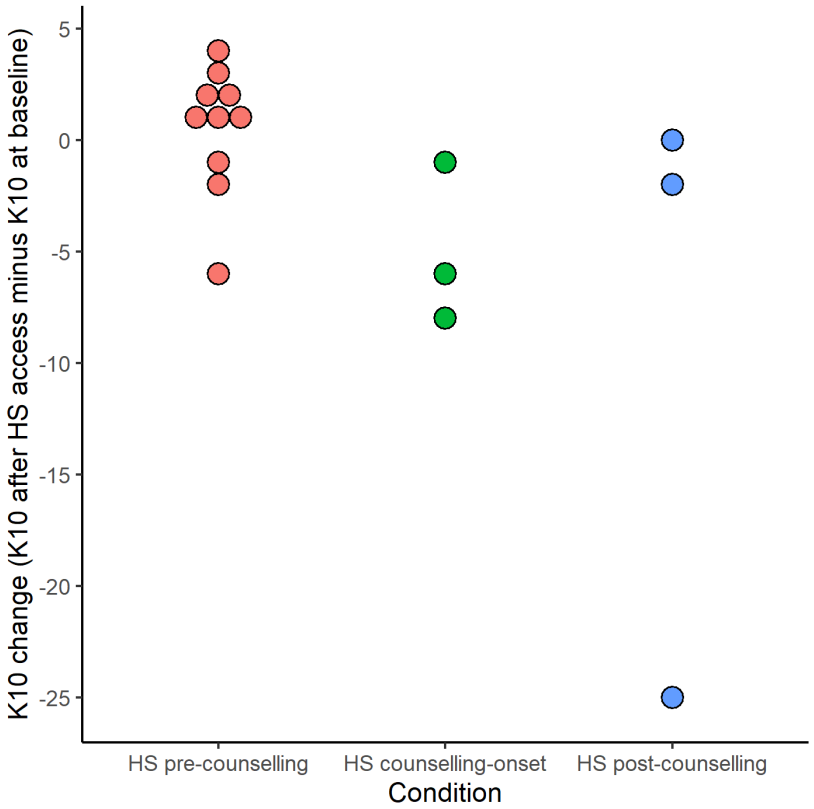

Figure 4.6. **Change in K10 after access to Headspace (HS) using available data.**

[39] For example, for pre-counselling participants the change score was K10 at start of counselling *minus* K10 at triage, or K10 at 2-week follow up *minus* K10 at triage. Where a participant completed both time points, the change score using the 2-week follow up was used. Positive scores indicated that K10 increased at follow up; negative scores indicated that K10 decreased at follow up.

4.4. Discussion

In the present study, I provided clinically distressed university students with 1 month of access to Headspace, a mindfulness meditation app. Participants received access to Headspace when they presented at the University of Otago's Counselling Service (pre-counselling), at the start of their counselling treatment (counselling-onset), or after they had finished counselling (post-counselling). Although I was unable to collect sufficient data to conduct the planned effectiveness analyses (and thus I am unable to provide support for or against any of the pre-registered hypotheses), I was able to descriptively analyse the severity of mental health needs of the students who were *willing* to participate in this style of intervention and use these data to comment on the needs of those accessing the service. Further, I was able to analyse app use data to show that even people who were recruited to this study with the understanding that they would receive this app may not follow through to download their app, which has implications for app use in complex clinical settings. Finally, using recruitment data and data collected from the study portal, I was able to characterise the fluctuating recruitment patterns over the course of this study and have used the disparity between 'participants approached' and 'participants registered in study portal' to identify where recruitment and implementation issues may occur. These descriptive analyses, allowed me to consider and discuss the successes and failures of this intervention in order to make suggestions for future research that is attempting to implement an intervention using a complex design with a diverse, but distressed, population.

4.4.1. Severity of mental health needs

I purposefully targeted a distressed population (i.e., those presenting at the University of Otago's counselling service for a range of distress-related reasons) to consider whether a mMBI would be helpful in reducing distress in this population. The sample who participated in this study demonstrated high levels of distress. For example, in a survey of Australian university student health services users (N = 1168), almost 9% of students had very high levels of psychological distress (K10 30-50, 8.9%, n = 104; Stallman & Shochet, 2009). By comparison, 61.4% of the current sample had very high levels of psychological distress (K10: 30-50). Admittedly, this is an

imperfect comparison as the Australian sample included all students attending student health services and not counselling specific students(Helen Margaret Stallman & Shochet, 2009). The clinical nature of this sample's distress is also apparent when compared to, for example, the nationally representative Aotearoa New Zealand community sample presented by Kvalsvig, New Zealand, and the Health Promotion Agency (HPA; 2018). The HPA reported that 21% of the general population have medium levels of psychological distress and 3% have high levels of psychological distress (the general population rate reported by HPA is consistent with Australian samples too; Stallman, 2010). Using the same cut-offs, one-hundred percent of our sample reported medium to high-level psychological distress. More specifically, over 60% of our sample reported high levels of psychological distress (K10: 30-50; Kvalsvig, New Zealand, & Health Promotion Agency, 2018).

The present sample of students reported high functional impairment, that is, on average they reported being unable to function at all for a week of the previous month with reduced functioning reported for 10 days on average in the past month. This rate of functional impairment consistent with previous reports from an Australian sample (very high distress was associated with 8 days not at all, and 9 days reduced; Stallman 2008). Such high functional impairment may directly impact the educational attainment of these students because they are unable to attend classes. In fact, heads of counselling services in New Zealand Aotearoa and Australian universities estimated that around 8% of students had mental health impairments that were severe enough that they would be unable to remain at university or could only remain with ongoing clinical help (range 2-30%; Stallman, 2012). Further, in a sample of 6,479 Australian university students, high distress (as measured by the K10) was associated with lower GPA (Stallman, 2010). Although it is unclear if this small sample of distressed students is representative of those attending the Student Health Service's counselling service, taken together, this high rate of distress and functional impairment is a cause for concern and further highlights the need to provide additional resources for these students in need.

4.4.2. Low app uptake but acceptable app use (among the less distressed)

Almost 70% of participants who were sent access to Headspace did not redeem their one month voucher (termed non-adoption in digital health; cf: Greenhalgh et al., 2017). Even so, app use by those who did receive the voucher was acceptable and higher than previous research would suggest is normal. That is, app-users (the 31% of participants who downloaded and used the app at least once), completed on average 10-sessions over the course of 16 days. By comparison, using real-life download and use data from suite of mental health apps, 5210 individuals downloaded one or more of the IntelliCare apps (Lattie et al., 2016). On average the apps were used 6 times over the course of 18 days (but these apps didn't have any constraints on how long they were available; Lattie et al., 2016). Importantly, those who those who accessed the app (n = 21 app users) were more mindful and less distressed, depressed, and stressed at baseline compared to those who did not use the app at all (n = 46), suggesting that those who needed the app the most, were the least likely to use it.

4.4.3. Recruitment and participant retention

Recruitment fluctuated over the course of the study, with higher recruitment observed at the start of Semester 2 2016 and Semester 1 2017. When identifying design flaws in a failed intervention study, it is important to distinguish between *implementation* failure and *intervention* failure (Mohr, Lyon, et al., 2017). In terms of recruitment and retention, I suspect that in this study it is a combination of the two. But it's not all bad news. In the following paragraphs I will outline implementation and intervention successes and failures. I will then describe specific factors that relate to the clinician and then specific factors that relate to the participant that may also have impacted on the success or failure of the study.

Implementation and intervention successes and failures

Sligo, Roberts, Gauld, Villa, and Thirlwall (2019) reviewed existing literature to identify the key elements of successful transformational change in health care organisations that are planning change. Although transformation change was not the goal of our study, the checklists

provide a good starting point for identifying the strengths and weaknesses of this study. These key elements were used to create a series of checklists for health care organisations planning change in terms of large-scale health information systems. Although these checklists were not available until well after I finished this trial, the research design was consistent with several of their recommendations but inconsistent with others. Below in Table 4.7., I present an adapted version of Sligo et al.'s (2019) recommendations and provide intervention-specific detail on how I succeeded and/or failed to plan and implement these elements within our organisation, Student Health Service's Counselling Service.

Table 4.7.

Project-specific implementation successes and failures as indicated by Sligo et al.'s (2019) Checklist for healthcare organisations undergoing transformational change.

Adapted checklist: Sligo et al., (2019)	Successes	Failures
Organisation understood/ consulted/ communicated to and with	This project was initially proposed by the Director of Student Health Services. I consulted with him many times to better understand the organisational structure, hierarchy, and allocation of resources.	The scope of my consultation was too narrow. I met with the Counselling team leader and my "local champion" (the clinical staff member who would be my main port of call and who other staff would inform of their needs), however, I should have met with other management and key staff without the company of the Director. This approach was perhaps too "top-down" and the power disparity may have meant that other management (e.g., the head of the counselling team) were less able to be honest about their thoughts on the project and how feasible it was.
Community understood/ consulted/ communicated to and with	I planned interviews with participants for *after* the intervention.	I did not conduct these interviews due to timing and I should have consulted with the community (distressed students/counselling service users) during the design phase.
Governance characteristics: Stable and supportive governance	Leadership in upper management was stable and supportive for the duration. Leadership within the clinical personnel was supportive in the early stages of the study. I built a strong relationship with one of the clinical team who agreed to be the "local champion" of the study.	My "local champion", Jodie, left the counselling team partway through the project and I was unable to build enough rapport with any other clinicians for them to fulfil the role. This lack of in-group-based leadership contributed to the project faltering in 2017. Further, the clinicians were facing their own employment challenges (the Mental Health Service Review). This review placed additional stress and burden on clinicians and ultimately their positions were restructured. During the service review, the team leader of the counselling service left and was replaced by an interim leader who was not supportive of the project.
External assessment and appraisal: External assurance, monitoring, evaluation	I conducted ongoing monitoring and evaluating of the process (regular consultation with clinical staff) and monitored data collection.	Although I planned to conduct preliminary analyses on a monthly basis, this fell to once every 3-4 months because I did not allocate enough time to this component and because recruitment was low there was not much change on a monthly basis.
Developing and maintaining a transformational hub: Instigation and maintenance of transformational hub with lead who has	Transformational change leader (i.e., the "local champion") helped me (and the research team) communicate with the clinical team. They developed buy-in within the clinical team while also advocating for their needs. They understood processes in place from both a clinical perspective and a research perspective and helped me and the	As previously, my "local champion", Jodie, left the counselling team partway through the project and I was unable to build enough rapport with any other clinicians for them to fulfil the role. This lack of in-group-based leadership contributed to the project faltering in 2017.

Adapted checklist: Sligo et al., (2019)	Successes	Failures
transformational change experience	clinical team instigate necessary changes and manage setbacks.	
Effective resourcing: Cost calculated and monitored **Adequate funding for staff training, secondment, replacement** **All potential sources of funding identified, including partnerships**	With the help of the Director, I instigated a relationship with the provider of the app, Headspace. We signed a MOU about our use of the app for research purposes. This allowed us free access to the app and participant user data (with their permission). In return, we were expected to send any published manuscripts to Headspace (after the fact). The MOU is available in Supplement 4.5.	I did informally approach the Director about additional resources for this project but this did not progress. Staff were expected to take part in consultation, training, and recruitment during their usual hours. I provided snacks during consultation with the clinical team as a koha towards their time.
Suitable workforce: Sufficient, knowledgeable project management staff employed & supported	The research team included upper level management (the Director), the "local champion" (practicing clinician on the team), the PI (a practicing clinical psychologist and experienced researcher) and myself (jack-of-all trades PhD student). The clinical team included middle management (Counselling team leader), the local champion (practicing clinician on the team), the counselling team members, and the administrative staff at the health service.	Sligo et al., recommends that where possible, people should be from the existing organisation so that they understand the underlying processes and culture within the context of the workplace. We initially had this, however, yet again when our local champion left we were unable to replace her.
Role of clinical personnel and communication: Involvement of clinical staff at all stages **Staff effectively informed, consulted and trained at all stages & reluctant staff issues addressed**	Clinical staffs' concerns and apprehension regarding change were acknowledged and alleviated through repeated consultation and flexible trial design. I included the clinical team in planning and implementing this intervention and the recruitment for this intervention within their workplace. This helped to reduce resistance and build trust. Clinical staff helped identify outcome measures that they believed would meaningfully inform their practice and provided solutions to tricky problems (e.g., the variation in length of treatment and how to contact the participants at specific time points). I prioritised face-to-face communication for clinicians who were directly affected by the implementation of this trial with ongoing changes to their usual workflow. Consistent with Sligo et al.'s suggestions, my form of communication with the clinicians primarily took the form of frequent, personal, engaging, brief presentations as well as roundtables where we sat together to discuss and brainstorm the barriers to	Although clinicians were engaged at all stages of the development of this project, they were primarily engaged as advisors rather than in decision-making roles. The clinical team were at first wary (during proposal), then engaged and motivated (during development and initial stages of recruitment), and then reduced engagement (during their service review and after the change of leadership).

Adapted checklist: Sligo et al., (2019)	Successes	Failures
	implementation and how to overcome them. Reluctant clinical staff received extra communication about the benefits of change. They were purposefully included in the planning processes and extra care was taken to troubleshoot their concerns.	
Information Technology: Existing and future technology platform and interoperability requirements identified & monitored. New technology is fit for purpose. Ongoing IT training is identified and resourced Relationships with external IT organisations clearly defined	To work best within the existing clinical practice, we built an automated and streamlined study portal that clinicians could log in to and use to register their clients. This portal served the function of automating all researcher-to-participant communication and also recorded clinician and participant data. It had a plain and simple to use interface and was iteratively built with consultation from the clinicians (e.g., additional functions were added in at their request). It was also built with specific clinicians in mind (one clinician was blind and so it had to be functional using screen reader software).	This portal was made to specification at the request of the research team and clinician team. It was practical at face-value, however, without more advanced programming understanding, I was unable to monitor the progress of recruitment and individual participants without requesting the data from the portal programmer. I believe the repeated changes to the portal were taxing to the programmer and did not facilitate our relationship. I wasn't aware of scope of the portal until it was in the progress of being built. The automated processes may also have alienated participants and contributed to survey attrition.

Factors specific to the clinician

Although clinicians indicated that they thought Headspace would be suitable for three-quarters of their new clients, they only invited approximately 15% of the (estimated) eligible population (189/1400). There are a number of reasons why this might be. First, the clinicians may have initially overstated their opinion of the suitability of mindfulness. Second, the burden of adding the recruitment may have made it infeasible within the timeframe of the consult. Third, the clinicians may have invited more clients, but may not have recorded when clients were not interested. Fourth, the clinicians may have lost interest in the trial. Fletcher, Gheorghe, Moore, Wilson, and Damery (2012) conducted a systematic review which identified factors that improved the recruitment activity of clinicians. Our study adhered to a number of these factors including communicating the research process, involving the clinicians in the research design phase, and adapting the recruitment procedures to better enable clinician to patient communication about the

trial during recruitment. There were a number of additional factors I overlooked. For instance, Fletcher et al., (2012) highlighted that trials with successful recruitment involve protected research time so that clinicians have enough time to discuss the trial with their clients and financial incentives for the clinicians for time spent on recruitment and training. In future trials, additional resources (both time and financial) would be a key priority. For example, there needs to be a longer buffer period at the outset of the study because clinicians were extremely motivated at this stage and approached many of their students but they needed more hands-on technical support to register the interest of those students in the study portal.

Further, I believe that the benefit to clinicians' workload was not tangible nor immediate enough. During the consultation process, the clinicians identified that *if Headspace was effective* it would be a useful tool to reduce pressure on them during the waiting period between triage and start of counselling. They deemed this possibility to be useful to them as clinicians. We, the research team, further anticipated that if Headspace was valuable to clients, then they would perhaps use fewer counselling sessions. We believed this would also be useful to clinicians (and their clients, obviously). Although these are important possible benefits, to get sustained buy in from clinicians a digital intervention "must fit into their workflows and offer some meaningful benefit rather than just adding another task to their work days." (Mohr, Weingardt, Reddy, & Schueller, 2017). Unfortunately, I do not believe that this meaningful benefit was realised; I think this trial ended up being "just another task" to add to their to-do lists. In future trials, Headspace or a digital intervention like it, may be more valuable as a "homework" component alongside counselling. As outlined in the literature review, individual practice is a predictor of intervention outcomes and yet it is a challenge to get participants to adhere to individual practice guidelines (e.g., Speca et al., 2000). Providing a brief and digital tool may help participants, or in this case clients, adhere to their treatment guidelines. The benefit to clinicians is that they would not need to find and assign "homework" to their clients and instead they could simply ask their client to complete *n* sessions in between now and their next counselling session. This would tangibly

reduce workload and offer immediate benefit for the clinician, while also perhaps, making it easier for clients to adhere to treatment guidelines.

Factors specific to participants

In terms of factors of intervention and implementation failure specific to participants, I would speculate that the following factors were implicated in the failure of this intervention: first, self-help tools may simply require too much self-motivation from clinically distressed students to be of benefit to them thus I should have consulted more closely with the distressed student community/counselling service users before designing the study (i.e., the opposite of a 'build it and they will come' approach). Second, the hands-off approach from the research team may have alienated participants.

Although a primary focus of this study was to establish effectiveness of app-based mindfulness in a diverse, clinically distressed student population, a planned sub focus was on investigating and supporting uptake and adoption. This sub focus was ultimately unrealised because although I used an iterative design method with clinicians, I did not involve clients in the design of this research trial. In retrospect, that was a mistake. When I first embarked on this research program, we [the research team and the treating clinicians] thought it was 'inappropriate' for me to have direct contact with research participants because I am not clinically trained and the participants were also my academic peers who were in a vulnerable state and it was important to protect their anonymity. In retrospect I think it would have been appropriate to invite clients to participate in a focus group or some other qualitative meeting with the understanding that I and other peers would be there during the design and consultation stage of this research. Within this context, I assume only clinically distressed individuals who were comfortable being identified would have opted into this option but still would have provided valuable insights into the clinically distressed student population, their wants, needs, and abilities to engage in an intervention like the current one. Had I consulted with student mental health service users I may have identified simple barriers (e.g., alienation through automated contact) or insurmountable

barriers (e.g., inappropriateness of the tool due to, for instance, low motivation from clinically distressed participants).

Although cumulative evidence from systematic reviews and meta-analyses suggest that digital interventions can have small-to-moderate effects on a range of clinical mental health conditions including depression and anxiety, reviews also generally conclude that support from a coach or clinician improves effectiveness (e.g., Christensen, Griffiths, & Farrer, 2009; Firth, Torous, Nicholas, Carney, Pratap, et al., 2017; Firth, Torous, Nicholas, Carney, Rosenbaum, et al., 2017). Mohr, Cuijpers, and Lehman's (2011). For example, the Supportive Accountability Model suggests that being accountable to someone improves adherence and thus outcomes. In a systematic review of 83 web-based interventions, Kelders, Kok, Ossebaard, and Van Gemert-Pijnen (2012), identified persuasive intervention design factors that improve adherence. Increased interaction with a clinician and in-built dialogue style support (e.g., tool provides praise, rewards, and reminders to the participant) were two of the key factors that predicted better adherence (Kelders et al., 2012). Emerging evidence also suggests that interpersonal support can be automated and that this automated support has comparable effects on participant outcomes and adherence as human support (Kelders, Bohlmeijer, Pots, & van Gemert-Pijnen, 2015). Building in greater interpersonal support, whether that be face-to-face with a clinician or as part of digital intervention may have serious impacts on not only adherence and uptake to an intervention, but also to participant outcomes. Here, I contacted participants about study matters using automated (although still friendly) emails but I didn't build in interpersonal support. I am on the fence about whether I should have in-built interpersonal support in this study. On the one hand, doing so would likely have increased adherence (both intervention and survey) and thus would have likely resulted in improved outcomes for participants. On the other hand, doing so would undermine the pragmatic and hands-off design of this study. That is, I didn't want to incorporate elements to the study that would not be provided if it were to be implemented in real practice for the fear that it would inflate the effect of the intervention beyond what would be realistically expected. A better option would be to investigate the existing features of Headspace that mimic the in-built dialogue

style support (e.g., tool provides praise, rewards, and reminders to the participant) that predicted better adherence (Kelders et al., 2012).

4.4.4. Limitations of the current results and future directions

This intervention was bold and ambitious but ultimately unsuccessful. Beyond the obvious limitation that I failed to collect the data required to answer the pre-specified research questions, there were several key limitations that should be used to qualify any interpretation of the results presented here.

First, the research design was too complex. The individualised treatment trajectories of patients meant there were different intervals between intervention time points (e.g., start of treatment and end of treatment). Because of these differing intervention time points, I had to rely on clinicians to trigger when a client started and finished treatment so that the online portal would send information to the participant. Relying on clinicians to do this added burden to their workload which was not feasible over the duration of the study. If I were to conduct an intervention study in this setting again, I would consider paring back the design so that I would be working more closely with one or two counsellors that were already using mindfulness as part of their practice. I would also create pen-and-paper study packs to be kept with the clients notes. At the start and end of their treatment, I would ask that the clinician provide the participant with their next survey. This could either be completed on site and left with reception, or it could be accompanied by a return post envelope. I believe that doing so would overcome some of the issues with data collection and would shift the burden from the clinicians to the researcher (i.e., in terms of data entry). It may also positively impact the likelihood of scaling up and sustaining the study. Keeping the design simple is consistent with recent digital health research guidelines; Greenhalgh et al., (2017) recently noted "The more complex an innovation or the setting in which it is introduced, the less likely it is to be successfully adopted, scaled up, spread, and sustained." (p. 2).

Second, it is unclear how well the implementation failures identified here will generalise to other settings. A unique and extenuating circumstance that occurred during this trial was that

the counselling team who were leading the recruitment for this study underwent a service review in the final semester of data collection. This service review led to a large-scale restructure of the mental health services provided at University of Otago's Student Health Service and ultimately led to the loss of all of the counselling roles and a disbanding of the counselling service in its then state (Higham, 2017). Although I had planned to conduct formal focus groups with the clinicians at the end of the trial (to formally supplement our ongoing consultation), upon news of the restructure, this was no longer considered appropriate nor sensitive to the needs of the clinicians whose roles were being restructured. For this reason, I cannot be certain that the service review impacted the sustainability of clinician engagement in the trial, however, I speculate that this did affect their interest in continuing to contribute to this research.

Third, although I recruited participants from a clinically distressed population, the recruitment rate was so low that it is likely that I recruited especially motivated participants. This sample was self-selected which may impact on the generalisability of this study. This is especially likely as over the course of the academic year Student Health Services counselling service was estimated to serve approximately 1400 students. Extrapolating that to 1.5 years (or three academic semesters) that means the sample from which we recruited may have been as high as 2000 students. Given I only recruited 86 people from this population, we are looking at less than 5% of the overall clinical population. Our sample, therefore, may not be representative of the student population who attend and use the Student Health counselling services.

Finally, to fully realise the potential of app-based mindfulness, it may be important to use even more flexible research designs than the iterative pragmatic RwCT used here. Several recent viewpoints and opinion pieces have discussed the relative merits and challenges associated with the gold standard randomised, controlled trial in the digital health research space (Greenhalgh et al., 2017; Mohr et al., 2013; Mohr, Lyon, et al., 2017; Pham, Wiljer, & Cafazzo, 2016). Several more have outlined alternative research designs and frameworks for evaluating these types of interventions (e.g., van Gemert-Pijnen et al., 2011). It is not clear what the 'gold standard' will be for digital health evaluation but what is clear is that a static (unchanging once initiated) clinical trial is not flexible enough to be a good investment of resources (Greenhalgh et al., 2017). In

future trials, if I were to implement this (or similar) intervention in a complex population (heterogeneous and likely co-morbid, as suggested by the presenting statistics) and complex environment (multiple interacting populations: researchers, patients, clinicians, teams, and overarching service providers), I would consider using Mohr, Lyon, Lattie, Reddy, and Schueller's (2017) Accelerated Creation-to-Sustainment (ACTS) model. ACTS is a design philosophy that uses two processes (design and evaluation) iteratively across three research phases (create, trial, and sustain) to produce a technology-based intervention that is sustainable in a real-world treatment setting. The focus on both implementation and effectiveness enables ACTS designed interventions to ultimately overcome the lag between research and practice (Bauer, Damschroder, Hagedorn, Smith, & Kilbourne, 2015). Ultimately, for digital tools to be of most value, they must be sustainable, acceptable, and sufficiently embedded within the available mental health services; anything less than that does not warrant the investment. Unless there is a "local champion" in place for the duration of the research projects, without the longer-term support of, and investment by, the university's mental health service, there is no way that the research project will produce valuable insights and long-term change. Future research trials should focus on the usability and acceptability to student-users and on methods on implementing these tools within existing mental health services.

4.4.5. Conclusion

Here, I presented data describing a university student population needing clinical intervention whose distress levels were very high. These university students were provided with a mindfulness meditation app; app uptake was low, but, when adopted, app-use was adequate. I also presented the lessons learnt from the failed implementation of a pragmatic randomised waitlist-controlled trial that provided access to a mindfulness meditation app—Headspace— to a clinically distressed student population who were seeking counselling at their University's Counselling Service. Although this intervention was unsuccessfully implemented within this setting, it provides important lessons to pave the way for future trials to be more successfully implementable within the existing Student Health Services context. On the basis of the data from

the current study, it is unclear whether Headspace is an *effective* tool for improving mental health in clinically distressed students but it is clear that (within the context of this research design) it wasn't the solution for an over-prescribed counselling service. Digital interventions, like Headspace, may be better suited as a component of existing counselling services, for instance as a homework component alongside counselling-as-usual.

4.4. Acknowledgements

I would like to thank and acknowledge the input of Dr. Kim Ma'ia'i (former Director of Student Health Services and advisor on this project), Jodie Black ('Local champion' [Greenhalgh et al., 2017] and clinician advisor on this project), and Andrew Gray (who provided statistical advice on this project). I sincerely thank Hadyn Youens who built the study platform. I thank Headspace for providing access to their mindfulness meditation program and user data. I would also like to sincerely thank the clinicians who provided their time and support for this project and finally, I would like to thank the students who took time out of their busy lives to take part in this research trial. This research was funded by the Office of the Vice-Chancellor, University of Otago.

CHAPTER 5: STUDY 3

App-based mindfulness meditation for psychological distress and adjustment to college in incoming university students: A pragmatic, randomised, waitlist-controlled trial[40]

5.1. Overview and Rationale

5.1.1. Clinical-level distress in university students

As outlined in earlier chapters, psychological distress is on the rise, particularly in young adults (Ministry of Health, New Zealand, 2018; Twenge, Cooper, Joiner, Duffy, & Binau, 2019). University students may be particularly vulnerable with clinical-level distress impacting between 20–45% of students and sub-clinical distress impacting over 60% of students (Auerbach et al., 2016; Auerbach et al., 2019; Leppink, Odlaug, Lust, Christenson, & Grant, 2016; Stallman, 2010). Among incoming first-year university students, approximately one-third have a history of at least one common DSM-IV mood, anxiety, or substance disorder (n = 13,984, 8 countries; Auerbach et al., 2019).

Despite the high prevalence of distress, only a fraction of clinically distressed students seek treatment (Blanco et al., 2008; Helen M. Stallman, 2010). Some evidence also suggests that help seeking is significantly lower in students than non-student (Blanco et al., 2008) and that the most distressed students are the least likely to seek treatment (Ryan et al., 2010). An additional concern is that, of those who seek treatment, only one in six students receive "minimally adequate" treatment (Auerbach et al., 2016). Given the high rates of distress, low rates of help-seeking, and low rates of acceptable treatment, I suggest that many clinically and sub-clinically distressed students exist in plain-sight who might benefit from an easily accessible intervention aimed at reducing distress.

[40] This chapter is an adapted version of the manuscript: Flett, J. A. M., Conner, T. S., Riordan, B. C., Patterson, T., & Hayne, H (In review). App-based mindfulness meditation for psychological distress and adjustment to college in incoming university students: A pragmatic, randomised, waitlist-controlled trial.

5.1.2. High stress during the transition to university

For incoming first-year university students, the transition from high school to university is a major source of stress (Ross, Neibling, & Heckert, 1999) that may contribute to or compound subsequent distress at university. Although beginning university can be a rewarding experience, it has also been associated with a number of negative outcomes including increased depressive symptomology, negative mood, physical health issues, concentration problems, homesickness, concerns about missing friends and family, and increased alcohol use (Price, McLeod, Gleich, & Hand, 2007; Pritchard, Wilson, & Yamnitz, 2007; Riordan & Carey, 2019). Notably, first-year university students report greater chronic stress levels, higher rates of depression, and lower rates of help-seeking than their later-year or graduate-level peers (L. M. Farrer, Gulliver, Bennett, Fassnacht, & Griffiths, 2016; Towbes & Cohen, 1996; Wyatt & Oswalt, 2013).

Chronic and high levels of stress have several problematic implications for student outcomes. Students report that stress is the number one barrier to academic performance ('American College Health Association-National College Health Assessment Spring 2008 Reference Group Data Report (Abridged)', 2009). Stress is also associated with lower academic achievement, and higher mental health problems, dropout, and drop-out intentions (Eicher, Staerklé, & Clémence, 2014; Leppink et al., 2016; Helen M. Stallman, 2010). In first-year students, stress levels predict lower adjustment to college (Chemers, Hu, & Garcia, 2001; Clinciu, 2013; Friedlander, Reid, Shupak, & Cribbie, 2007) which in turn, also predicts academic achievement, retention, and degree attainment (Credé & Niehorster, 2012).

The high rates of chronic stress in first-years coupled with the increased risk of mental health and academic adjustment problems, suggests that for many first-year university students, the transition to university represents a period of increased risk of adverse outcomes that may have long-term impacts for the individual. Given that this transition to university is also associated with greater changes of existing behaviours (Wood, Tam, & Witt, 2005) the transition period may also provide a window of opportunity to ameliorate clinical and sub-clinical distress. Interventions

aimed at reducing stress or distress during the transition period to university may lead to better mental health, student adjustment, and university completion.

5.1.3. Digital mindfulness-based interventions

Mindfulness meditation is often used as a psychotherapeutic intervention in clinical and non-clinical populations (Creswell, 2017). In-person and digital mindfulness training is associated with small to moderate improvements in stress, depressive symptoms, anxiety, pain, and well-being (for relevant meta-analytic reviews see: Cavanagh, Strauss, Forder, & Jones, 2014; Goyal et al., 2014; Spijkerman, Pots, & Bohlmeijer, 2016) and may enhance the transition to university (pilot: Dvořáková et al., 2017; review: Shapiro, Brown, & Astin, 2011). Emerging research also demonstrates that app-based mindfulness training may improve university students' symptoms of depression, college adjustment, resilience (Flett, Hayne, Riordan, Thompson, & Conner, 2019) stress, and mindfulness (Lyzwinski et al., 2019; Yang et al., 2018). App-based mindfulness training could therefore be a promising tool to reduce distress among incoming first-year university students.

Although research into their effectiveness is in its infancy, mindfulness meditation apps overcome many of the barriers associated with in-person training (Mrazek et al., 2019). As with internet-based interventions, delivering mindfulness meditation training using an app allows for wider availability, anonymity, accessibility at any time or place, user-flexibility in frequency or amount of use, and standardisation of intervention content and presentation (Dorsey et al., 2017; Mrazek et al., 2019). Given that the preference for digital psychotherapeutic interventions is increasing (Renn, Hoeft, Lee, Bauer, & Areán, 2019) and that younger adults, higher education, and higher distress are factors that predict greater preference for online mental health interventions and lower preference for face-to-face therapy (Batterham & Calear, 2017; Ryan et al., 2010), app-based mindfulness training may represent a promising intervention option for first-year university students. By intervening during the transition to university, we may be able to reduce distress and improve adjustment (Dvořáková et al., 2017).

5.1.4. The current study

Here, I report the findings of a two-arm pragmatic, randomised, waitlist-controlled trial (RWCT) in which university students living in first-year residential colleges (dormitories) received three months' access to Headspace–a widely used mindfulness meditation app–in the first (intervention condition) or second semester (waitlist condition) to use at their discretion. Mental health interventions targeting students living in first-year residential colleges provide an opportunity to access a large and diverse vulnerable population. I hypothesised that:

> **H1:** access to a mindfulness meditation app in semester 1 would be associated with improvements in psychological distress at the beginning of semester 2, as compared to a waitlist (Primary hypothesis).
>
> **H2:** there would be a 'dose-response relationship' between app use and psychological distress, such that those who used the app most frequently would reap the greatest benefits.
>
> **H3:** the hypothesised associations in (H1) and (H2) would extend to the other mental health outcomes measured in the current study (college adjustment, resilience, self-efficacy, and mindfulness).

5.1. Methods

5.2.1. Design

The study consisted of a pragmatic RWCT investigating the effect of mobile mindfulness meditation on mental health in an incoming student population at the University of Otago. Participants were randomly assigned to one of two conditions (1:1 allocation ratio), receiving Headspace during semester 1 (intervention), or receiving Headspace during semester 2 (waitlist). This trial and outcome measures were registered prior to recruitment with the Australia and New Zealand Clinical Trials Registry (ACTRN12617000300370[41]). A range of mental health measures were assessed. The pre-registered measures were K10 distress as the primary outcome, and college adjustment, resilience, self-efficacy, mindfulness, and academic grades as the secondary outcomes. All measures, except academic grades, were collected at three time points: at the beginning of

[41] We registered this protocol for two populations: incoming university students and university staff. We did not receive Human Resources approval to proceed with the university staff trial.

semester one (Time 1), at the beginning of semester two (Time 2) and at the end of the academic year (Time 3). Academic grades were provided by the university at the end of the academic year with consent from participants. Objective app use data were provided by Headspace. As a pragmatic trial, the research design was intended to "maximise applicability of the trial's results to usual care [real-world] settings" (Zwarenstein et al., 2008, p.2). Data were collected from March (recruitment, Time 1) through to December 2017 (Time 3).

To be eligible for this study, participants had to be first-year students residing in one of two residential colleges and had to be at least part-time University of Otago students. To take part in the RWCT, participants also had to own an iOS or android smartphone or be willing to use the Headspace desktop version on their personal computer or laptop.

5.2.2. Sample size and randomisation

This design required a sample size of at least 100 participants per randomised condition to provide 80% power to detect a d = .4 effect size on the K10 measure of distress using a two-sided test at the 0.05 level. As indicated in the CONSORT diagram (Figure 5.1.) I nearly achieved this target at our primary time point, the beginning of the second semester (Time 2: n = 195, 97.5% of required n), but were unable to meet this goal at our secondary time point, the end of the academic year (Time 3: n = 94, 47% of required n). Randomisation was stratified based on gender and college (information provided in the baseline survey). The first author (JF) randomised participants by splitting the files by gender and college (females College 1, males College 1, females College 2, males College 2; gender identification was free-text, no participants identified as gender diverse). Using an excel random number generator (formula =rand()) to randomly assign a value between 0.00001-0.99999 to the split files, these values were than rounded to 0 (waitlist) or 1 (intervention). Experimenters were not blinded to condition but did not have any unautomated/unstandardised interaction with participants; participants were not blinded to condition as this was not possible in a waitlist control.

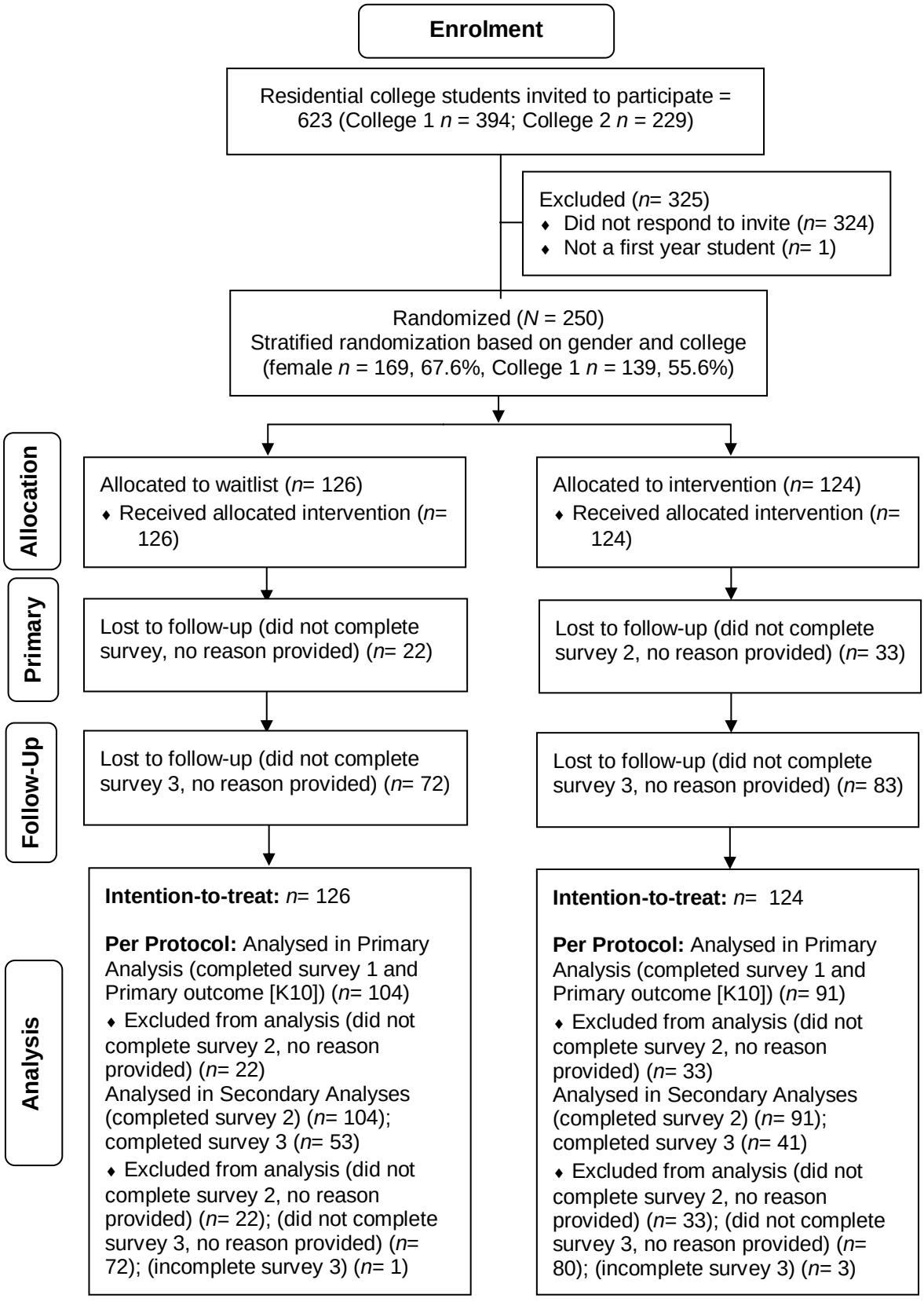

Figure 5.1. **CONSORT diagram of study participation.**[42]

[42] An additional 21 undergraduate students agreed to complete surveys but had no desire to trial Headspace. Where data were available, these studens did not differ from included participants.

5.2.3. Participants

Participants were 250 undergraduate students between 17 and 20 years old (*M*=17.87 years, *SD*=.47 years; 67.6% women, 32.4% men) recruited from two residential colleges at the University of Otago, Dunedin, New Zealand. Participants were largely of New Zealand European/Pākehā descent (80.2%; 11.2% Māori or Pasifika; 7.2% Asian; 3.2% Indian; 13.2% other; ethnicity data is expressed as a percentage because participants may identify with more than one ethnicity) which generally reflected the wider university community. Fifty-five participants did not complete Time 2 measures and thus were excluded from per protocol analyses (see Figure 5.1. CONSORT diagram and Supplemental Table 5.1. for PP participant characteristics). Participants were recruited by email during March 2017. Informed consent was obtained from all individual participants included in the study. This study was approved by the Department of Psychology with oversight from the Human Ethics Committee (D17/029).

5.2.4. Procedure

Two residential colleges provided the contact details of their residents after the researcher (JF) described the study to students for two minutes at a start of year assembly. All residents were invited to participate by email. After providing consent, residents completed an online baseline survey (Time 1; the beginning of semester 1). Following randomisation, participants in the intervention condition were sent a personalised email with app download instructions and a code entitling them to three months' access to Headspace. I recommended that participants select a regular time and place (e.g., every morning upon waking – in your bedroom) to use their app to help create a habit of use. They were made aware of the reminder and 'mindful moment' functions available within the app (push notification e.g., 'We can get swept away and overwhelmed by our thoughts or learn to step back and see them with clarity. It's easy to forget it's a choice'). In this pragmatic RWCT, app use was encouraged but not mandated, and so was at the discretion of the participant. Participants in the intervention condition were also sent six text messages over the course of the semester reminding them to download and use their app during semester 1. Participants in the waitlist control did not receive text messages during semester 1. The app

download and text reminder procedure was repeated for waitlist participants at the beginning of semester 2 following the end of the Time 2 survey. Participants in the intervention condition did not receive text messages during semester 2.

Online surveys (excluding demographic questions) were repeated at the beginning of semester 2 (Time 2) and the end of the academic year (Time 3). Participants were given two weeks to complete surveys; non-responders received two automated text and email reminders. To encourage completion of surveys, all participants were entered into a lottery for a $200 gift card for each survey they completed.

5.2.5. Application

Headspace

Headspace is a mindfulness meditation application that provides guided and unguided mindfulness meditations. Meditation training is provided by Andy Puddicombe, a novice monk in the Theravada Tradition and fully ordained Tibetan Buddhist monk in the Karma Kagyu Lineage (Puddicombe, n.d.-b). Headspace uses a variety of formal meditation practices to build mindfulness including mindful breathing (using the breath as an attentional object of intense focus), body scan (systematically focusing on certain parts of the body), sitting meditation, practice of non-judgment of thoughts and emotions, and other guided meditations that vary the orientation (inward vs. outward vs. no orientation), spatial focus (fixed vs. moving), and aperture of attention (narrow vs. diffuse). Headspace is available as an iOS, Android, and web app. The length of meditations varies, however: participants completed a 10-minute per day, 10-day introduction to mindfulness (available free of charge), before accessing other meditation training in the app (available following purchase; meditations used here ranging from 1 to 20 minutes). Access to the participants' objective Headspace app use data was provided by Headspace (*Memorandum of Understanding* available in Supplement 4.5.).

5.2.6. Measures

Demographic characteristics

Participants provided basic demographic characteristics including age, gender (free text), ethnicity (New Zealand European/Pākehā, Māori, Samoan, Cook Island Māori, Tongan, Niuean, Chinese, Indian, Other – free text; participants may identify with more than one ethnicity), and the name of their residential college.

Distress

Distress was assessed using the 10-item Kessler Psychological Distress Scale (K10; Kessler et al., 2002). Distress was pre-registered as the primary outcome in this study. Responses were summed to create a score from 10–50, with higher scores indicating higher psychological distress (Andrews & Slade, 2001). This scale has acceptable convergent and discriminant validity (Feldman et al., 2006). Here, αs were .851, .896, .875 at Time 1, Time 2, Time 3, respectively.

College adjustment

College adjustment was assessed using the 19-item College Adjustment Test (Pennebaker et al., 1990), which captures experiences related to adjusting to college life in terms of positive affect, negative affect, and homesickness (subscales). Items were reverse scored where appropriate and summed to create a score from 19–133, with higher values indicating greater adjustment to college. This scale has good test-retest reliability (Pennebaker et al., 1990). Here, αs. were .875, .881, .865 at Time 1, Time 2, Time 3, respectively.

Resilience

Resilience was assessed using the six-item Brief Resilience Scale (Smith et al., 2008), which aims to measure of the ability to bounce back or recover from stress. Responses were averaged across the six items to obtain a score for each participant ranging from 1–5, with higher scores indicating greater resilience. This scale has good test-retest reliability and acceptably convergent and divergent validity (B. W. Smith et al., 2008). Here, αs. were .860, .883, .881 at Time 1, Time 2, Time 3, respectively.

Self-efficacy

Perceptions of self-efficacy were assessed using the eight-item New General Self-efficacy Scale (Chen et al., 2001), a measure that assesses how much people believe they can achieve their goals, despite difficulties. Responses were summed over the eight items to obtain a score for each participant ranging from 8–40, with higher scores indicating greater self-efficacy. This scale has good test-retest reliability, content, and predictive validity (Chen et al., 2001). Here αs were .870, .890, .904 at Time 1, Time 2, Time 3, respectively.

Mindfulness

Mindfulness was assessed using the 12-item Cognitive Affective Mindfulness Scale – Revised (Feldman et al., 2006), a scale consisting of several facets of mindfulness including attention, present focus, awareness, and acceptance. Responses were summed over the 12 items to obtain a score for each participant ranging from 12–48, with higher scores indicating a greater level of the mindfulness facets: attention, present focus, awareness, and acceptance. This scale has good convergent and discriminant validity (Feldman et al., 2006). Here, αs. were .753 .768, .843 at Time 1, Time 2, Time 3, respectively.

Academic achievement

Academic achievement was assessed using participants' averaged semester 1, semester 2, and overall academic scores (out of 100). These data were provided by the University of Otago with the participants' permission. For transparency, academic achievement was a preregistered outcome but there were no statistically significant findings for any analyses involving academic achievement and thus, for brevity, these analyses are available in Supplement 5.2.

App use and app experiences

As part of the information and consent process, participants agreed to allow Headspace to provide researchers with user data. For each participant, I was provided with the date and time of each app use session, session duration (in minutes), session type (which content in Headspace they used), and status (completed vs. uncompleted). I analysed these metrics to determine the number of meditation sessions they completed, the amount of time spent meditating, and the types of meditation content they were accessing.

I also asked participants to rate their perceptions of mindfulness meditation using two questions ('How useful do you think mindfulness meditation would be for yourself [Time 1]/has been for yourself [Time 2, Time 3]?' and 'How effective do you think mindfulness would be for yourself [Time 1]/ has been for yourself [Time 2, Time 3]?') on a scale from one [Not at all] to four [Very useful]. Scores on these two items were correlated (rs > .630) and averaged at each time point. Higher scores indicated a higher overall positive expectation (at Time 1 [all conditions] and Time 2 [waitlist condition]) or perception (at Time 2 [intervention condition] and Time 3 [all conditions]) of usefulness and effectiveness of mobile mindfulness meditation. These measures were not considered outcomes and thus were not preregistered. At Time 1, participants also reported whether they had previous experience with mindfulness ('Have you ever practised mindfulness before?'; response 0: no, 1: yes, 2: unsure).

5.2.7. Other considerations

Trial safety and harms

All student participants remained under the pastoral care of their Residential College and the college's Sub-Wardens. To minimise risk to participants, if individuals experienced increased distress by taking part in this project and using the mindfulness app, they were advised to cease mobile mindfulness meditation. Participants were asked to continue completing surveys of their mental health outcomes during their study participation even if they terminated use of Headspace. If the distress was prolonged or marked or they were concerned, they were informed to contact the institution's Student Health Services where an MD and clinical psychiatrist were available to conduct clinical assessments to determine the appropriate response to the participants' experience, facilitate participant treatment, and report the occurrence, severity, and management of the adverse event to the research team within a 48-hour time period. If 2+ participants reported adverse experiences with the app, the research team were to meet to decide whether the trial would be terminated; if so, all participants and the residential colleges were to be contacted immediately. To our knowledge, no participants used the clinical assessments. One participant asked for their distress scores to be supplied to their doctor; I complied with this request.

At the outset of this study, harms in brief mindfulness meditation practice were not well understood (cf. Van Dam et al., 2018). In addition to open-ended questions asking participants to identify any unexpected, challenging, or difficult experiences they had with their mindfulness practice, a dichotomous (yes = 1, no = 0) list of 59 potential meditation-related challenges (identified from a mixed methods study of predominantly experienced Buddhist meditators; Lindahl, Fisher, Cooper, Rosen, & Britton, 2017) was an ad hoc addition to the Time 3 survey in an attempt to identify potential harms. These additions were approved amendments to our ethical protocol (D17/029) and were not subject to multiple imputation. Participants reported experiencing 7.14/59 meditation related challenges on average (SD = 4.91); however, (using the objective app use data) there were no differences in average number of reported meditation-related challenges between those who used the meditation app one or more times and those who did not use it at all ($F(1,84) = .01$, $p = .918$) suggesting that caution is warranted when interpreting these data. Further, some of the challenges included on the checklist could be interpreted in a positive or negative way, especially for novice meditators or those without Buddhist training (e.g., change in world view; laughing).

5.2.8. Data analyses

In line with best practice, I analysed data following an 'intention-to-treat' (ITT) approach (Altman, 2009) and thus present both ITT and Per Protocol analyses. Our primary analysis examined psychological distress change scores (as measured by K10, Kessler et al., 2002) from baseline (Time 1) to the primary follow-up time point (Time 2: semester 2, Week 2) between conditions (intervention vs waitlist). In secondary analyses, I examined changes in resilience, mindfulness, self-efficacy, college adjustment and academic achievement from Time 1 to Time 2 and Time 1 to Time 3 between the two conditions (intervention vs. waitlist; independent sample t-tests) and within conditions over time (paired sample t-tests). Analyses at Time 2 assess the primary manipulation (app access vs. no app access) and short-term effects of the intervention on outcomes (intervention condition); analyses at Time 3 assess longer-term effects (intervention condition) and effects in waitlist condition (following provision of the intervention). I also examined whether

objective app use predicted the change in psychological distress and secondary outcome variables at Time 2 and Time 3 (with the Time 1 outcome included as a covariate). In all models, I had originally controlled for participants' age, gender, ethnicity, previous experience with mindfulness, app expectation and app perception scores, but removed them from the final models because they did not change the interpretation of the results. When examining the change scores by app use plots, it became apparent that app use was better characterised categorically as *Non User* (0–3 times across the three months' access), *Low User* (4–8 times across the three months' access), and *Moderate User* (9+ times across the three months access). Categorical app use was thus dummy coded to establish whether there were differences in outcomes between the Non Users, Low Users, and Moderate Users (there were no baseline differences between these groups *p*s< .131). Models with app use as a continuous measure are available in the Supplemental results 5.3 and 5.4. I followed Bender and Lange's recommendations regarding corrections for multiple hypothesis testing in planned analyses (Bender & Lange, 2001). For the primary analysis (ITT and PP), an unadjusted p-value of < .05 was considered statistically significant. For the secondary analyses, p-values were adjusted using a conservative Holm-Bonferroni sequential correction (calculator available: Gaetano, n.d., Holm, 1979). I performed separate multiplicity corrections for 1) tests examining change in mental health by condition (reported in Tables 5.2. and 5.3.) and 2) for tests examining change in mental health by frequency of app use (reported in Table 4). I performed these multiplicity corrections for intention-to-treat and per-protocol analyses separately as they represented the same tests. Both adjusted and unadjusted p-values are presented for transparency. In line with van Ginkel et al.'s recommendations for when combination rules are unavailable, for the ITT analyses I used an ad-hoc method to calculate the effect size (and their associated 95% confidence intervals; van Ginkel, Linting, Rippe, & van der Voort, 2019). I calculated the effect size for each imputed dataset individually and then averaged the values to get to a pooled result. Effect sizes and confidence intervals for Cohen's *d* were calculated using Laken's adapted version of Wuensch's guide (which itself is adapted from Smithson's guide; Lakens, 2014; Smithson, 2001; Wuensch, 2012).

To remain consistent with Studies 1 and 2, I conducted post-hoc correlational analyses to determine whether any demographic or baseline mental health characteristics predicted objective app use.

5.2.9. Missing Data

Overall there was 26.45% missing data. Recalling that Headspace provided us with participants' objective app use, at Time 2 and Time 3 I have objective app use data for 14 participants who did not complete the surveys of their mental health at Time 2 (5.6% of original randomised sample). Overall 22% of participants at Time 2 and 62.4% of participants at Time 3 were survey non-adherent (i.e., lost to follow-up). There were several instances of scale non-response whereby a participant missed one or more whole scales (e.g., the brief resilience scale)(B. W. Smith et al., 2008) seemingly due to abandoning the survey partway through (Time 1: 0–.4%; Time 2: 0–1.0% Time 3: 0% scale non-response, min. cases per scale = 0, max cases per scale = 2). These data were considered missing at random.

For the intention-to-treat (ITT) analyses, missing data were imputed at the item-level (20 iterations in line with recommendations; Graham, Olchowski, & Gilreath, 2007) using the multiple imputation process in SPSS version 25 (IBM Corp., 2017). I used fully conditional specification (an iterative Markov chain Monte Carlo method) and predictive mean matching (PMM) to constrain scale values to plausible values (PMM is also more robust to violations of normality; van Ginkel et al., 2019). SPSS version 25 supports the planned analyses using pooled multiply imputed data but uses an approximation of degrees of freedom (*df*) which often results in inflated df; for transparency I have provided the pooled df as provided in the analyses output. App use data were not imputed as they were objective measurements of adherence and thus imputation was neither necessary nor appropriate. For the per protocol analyses (PP), I analysed cases where participants provided data and used pairwise deletion for analyses of variables with item-level or scale-level missingness. I report ITT alongside PP analyses where possible; additional analyses are available in the Supplementary results 5.5. and 5.6.

5.3. Results

The results are reported in four sections: In the first section, I report descriptive statistics for the demographics and baseline mental health measures, and the frequency and expectations of app use. In the second section, I report the changes in mental health over time (within condition) and as a function of when the app was received (between condition) for the primary and secondary outcomes (H1 and H3). In the third section, I report the app use frequency as a predictor of mental health (H2). In the fourth section, I report correlational analyses to determine whether any demographic, personality, or baseline mental health characteristics predicted self-reported app use (A: during the 10-day trial where adherence was requested and B: during the 30-day period where use was at the discretion of the participant).

5.3.1. Descriptive statistics and app use characteristics

As shown in Table 5.1., there were no significant differences between all randomised conditions in any of the demographic or baseline mental health measures by condition (all *p*s > .158); this was also true of those retained for per protocol analyses (Supplementary Table 5.1.). Excluding distress, participants' average scores for the baseline characteristics fell into the commonly accepted normative ranges (e.g., resilience > 3; Smith et al., 2008). Although distress scores were higher than previous reports (here: 46.4% scored 20+ vs. 12.1% (Andrews & Slade, 2001) they are consistent with the notion of higher rates of clinical-level distress in student samples.

As shown in Table 1, app use was low and practice and expectations about the app dropped off over the course of the study, but the patterns of uptake differed by condition. Participants who received the app in the first semester (intervention condition) were more likely to initiate and continue practice beyond the first week than those who received the app later in the year (waitlist condition). Further, despite unrestricted access to the Headspace app for three months (and intermittent reminders about access from the research team), app use remained very low on average (approximately two times per month) across both intervention and waitlist participants. Although there were no significant differences between conditions in the number of meditation sessions completed, the same was not true of the number of minutes meditated. Intervention participants

meditated on average approximately 15 minutes longer than waitlist participants during the first month of access and approximately 30 minutes longer overall, although the overall difference was not statistically significant. These app use differences were more pronounced in the per protocol analyses (Supplementary Table 5.1.). Finally, although there were no significant differences in baseline expectations of mindfulness between intervention and waitlist conditions, the positive expectations of the app dropped in both conditions after participants had been provided access to the app. That is, there was a significant difference between conditions at Time 2, but not at Time 3 when both conditions had received access to Headspace. This tendency for the app to not live up to expectation (as indicated by reduced positive expectation following use) was further supported by statistically significant paired t-tests for each condition after access to the app (ITT: Intervention Time 1–Time 2 $t(50) = 3.06$, $p = .004$; Time 1–Time 3 $t(85) = 2.77$, $p = .007$. Waitlist Time 1–Time 2 $t(56) = .79$, $p = .433$; Time 1–Time 3 $t(147) = 2.23$, $p = .027$), but the magnitude of this drop-in expectations was not particularly large (less than .5-point drop on a 4-point scale).

Table 5.1.

Equivalency of baseline characteristics (Time 1: top rows) and app use characteristics (bottom rows) overall and by condition.

	Overall *n* = 250		Waitlist *n* = 126		Intervention *n* = 124		One-way ANOVA (Chi-square)		
	M	*SD*	*M*	*SD*	*M*	*SD*	*F* (X^2)	*df*	*p* (Sig)
Age (years)	17.87	0.47	17.86	0.47	17.89	0.48	.25	1, 248	.618
Gender (female; *n* %)	169	67.7	71	68.3	67	73.6	.00	1	.962
Ethnicity (NZ Euro; *n* %)	202	80.8	99	78.6	103	83.1	.81	1	.367
Distress [1]	19.71	5.46	19.41	5.51	20.01	5.42	.74	1, 248	.390
College adjustment	83.46	16.30	84.71	16.31	82.19	16.26	1.49	1, 248	.224
Positive affect	31.48	5.20	31.94	5.36	31.01	5.00	2.00	1, 248	.158
Negative affect	35.40	10.52	34.71	10.78	36.10	10.24	1.09	1, 248	.297
Homesickness	24.16	7.28	23.96	7.02	24.37	7.56	.20	1, 248	.657
Resilience	3.37	0.69	3.43	0.65	3.31	0.74	1.94	1, 248	.165
Self-efficacy	30.09	4.55	29.89	4.68	30.29	4.44	.49	1, 248	.487
Mindfulness	30.71	5.02	31.00	5.20	30.41	4.83	.86	1, 248	.365
Practicing ≥ 1 day (*n* %)	138	55.2	56	44.4	82	66.1	11.88	1	.001
Practicing ≥ 1 week (*n* %)	98	39.2	41	32.5	57	46.0	4.73	1	.030
Practicing ≥ 4 weeks (*n* %)	68	27.2	28	22.2	40	32.3	3.18	1	.075
Practicing ≥ 6 weeks (*n* %)	52	20.8	21	16.7	31	25.0	2.64	1	.105
Practicing ≥ 3 months (*n* %)	17	6.8	6	4.8	11	8.9	1.67	1	.197
Practice duration (days)	19.64	30.10	16.25	28.38	23.07	31.49	3.24	1, 248	.073
n meditation sessions	6.96	13.86	6.02	12.44	7.91	15.16	1.17	1, 248	.281
Minutes meditated 4 weeks	33.26	59.53	25.52	49.59	41.14	67.46	4.36	1, 248	.038
Minutes meditated overall	65.50	151.52	51.90	144.29	79.32	157.90	2.06	1, 248	.153
Expectations (Time 1)	3.12	.56	3.08	.51	3.16	.61	1.27	1, 246	.261
Expectations (Time 2)	2.90	.75	3.04	.52	2.76	.73	10.03	1, 193	.002
Expectations (Time 3)	2.87	.74	2.88	.70	2.88	.82	.03	1, 96	.875

Note: *M* = Mean, *SD* = Standard deviation. [1] Distress from the K10 was the preregistered primary outcome variable.

5.3.2. Changes in mental health between conditions and within conditions

In Table 5.2., I present independent t-tests comparing change scores in mental health outcomes by condition. There was weak and conflicting evidence for our primary hypothesis (H1) that access to a mindfulness meditation app would be associated with improvements in psychological distress over time. That is, in the ITT data there were no statistically significant change score differences between conditions; although this test was underpowered, both conditions appear to have slightly increased distress at Time 2 and slightly decreased distress at Time 3. By contrast, in the PP data, access to the mindfulness app in Semester 1 (intervention condition) was associated with small improvements in psychological distress over time. More specifically, intervention participants reported statistically significant improvements in distress from Time 1 to Time 2 compared to the waitlist control group, who reported a small increase in distress. But, as indicated by the 95% confidence intervals for the effect size, the specificity of this effect ranges from very small to medium (d = .39; 95% CI: .10 to .67). Taking both ITT and PP analyses into account, I suggest there is only weak support for H1.

Similar patterns were reported with college adjustment, negative affect and mindfulness (H3) in ITT and PP analyses, however after adjusting for multiple testing, only improvements in mindfulness were retained in the PP analyses and the specificity of the mindfulness effect ranges from small to medium (d = -.47; 95% CI: -.76 to -.19). Moreover, significant differences in change scores between conditions at Time 2, but not Time 3, may suggest that improvements in psychological distress and mindfulness at Time 2 reflect the impact of the intervention. Further the non-significant differences in change scores at Time 3 suggest the waitlist participants' mental health outcomes may be comparable to the intervention group after they had received the intervention. Interpretation of these results should be made with caution due to the nature of these data (ITT vs. PP) and the low power of these tests.

Table 5.2.

Independent paired t-tests comparing outcome change scores (Time 2 = Time 2 – Time 1: top rows; Time 3 = Time 3 – Time 1: bottom rows) between conditions.

	Intention-to-treat					Per-Protocol				
	Waitlist	Intervention				Waitlist	Intervention			
Change score T2-T1	*M* (SD)	*M* (SD)	*t* (*df*)	*p* (*p'*)	*d* [95% CI *d*]	*M* (SD)	*M* (SD)	*t* (*df*)	*p* (*p'*)	*d* [95% CI *d*]
Distress	**1.82 (5.90)**	**1.16 (6.89)**	**.76 (727)**	**.450 (na)**	**.10 [-.13, .35]**	**.81 (4.78)**	**-1.11 (5.19)**	**2.69 (193)**	**.008 (na)**	**.39 [.10, .67]**
College adjustment	-.78 (14.57)	3.07 (17.14)	-1.76 (518)	.079 (1.00)	-.22 [-.49, .01]	.50 (12.96)	5.65 (15.25)	-2.55 (193)	.012 (.348)	-.37 [-.65, -.08]
Positive affect	-2.85 (5.53)	-2.50 (5.72)	-.42 (232)	.673 (1.00)	-.08 [-.33, .16]	-2.37 (5.11)	-1.60 (4.96)	-1.05 (193)	.294 (1.00)	-.15 [-.43, .13]
Negative affect	-1.04 (9.07)	-4.00 (11.13)	2.11 (456)	.036 (1.00)	.29 [.04, .54]	-1.71 (8.01)	-5.53 (9.69)	3.01 (193)	.003 (.098)	.43 [.15, .72]
Homesickness	-1.21 (7.13)	-2.32 (8.21)	1.06 (797)	.289 (1.00)	.15 [-.10, .39]	-1.60 (6.27)	-2.98 (7.34)	1.42 (193)	.158 (1.00)	.20 [-.08, .49]
Resilience	-.08 (.61)	-.01 (.68)	-.68 (110)	.497 (1.00)	-.12 [-.37, .13]	-.04 (.55)	.05 (.58)	-1.10 (193)	.271 (1.00)	-.16 [-.44, .12]
Self-efficacy	-.75 (4.34)	-1.21 (5.10)	.07 (395)	.486 (1.00)	.10 [-.15, .34]	-.22 (3.46)	.03 (3.92)	-.48 (191)	.630 (1.00)	-.07 [-.35, .21]
Mindfulness	-.96 (4.33)	.51 (4.98)	-2.39 (2624)	.017 (.578)	-.31 [-.56, -.06]	-1.15 (3.42)	.69 (4.36)	-3.29 (191)	.001 (.042)	-.47 [-.76, -.19]
Change score T3-T1	*M* (SD)	*M* (SD)	*t* (*df*)	*p* (*p'*)	*d* [95% CI *d*]	*M* (SD)	*M* (SD)	*t* (*df*)	*p* (*p'*)	*d* [95% CI *d*]
Distress	-1.20 (5.93)	-1.74 (5.89)	.69 (1143)	.489 (1.00)	.09 [-.16, .34]	-1.68 (6.00)	-3.24 (5.56)	1.29 (92)	.199 (1.00)	.27 [-.14, .68]
College adjustment	8.88 (16.90)	11.01 (17.62)	-.94 (3171)	.347 (1.00)	-.12 [-.37, .13]	8.62 (16.69)	14.40 (18.67)	-1.58 (92)	.118 (1.00)	-.33 [-.74, .08]
Positive affect	-1.35 (6.32)	-.37 (5.55)	-1.25 (1883)	.211 (1.00)	-.17 [-.41, .08]	-2.02 (7.08)	-.56 (6.05)	-1.05 (92)	.295 (1.00)	-.22 [-.63, .19]
Negative affect	-4.86 (11.31)	-6.35 (11.41)	1.01 (3250)	.313 (1.00)	.13 [-.12, .38]	-5.53 (11.08)	-9.22 (11.71)	1.56 (92)	.122 (1.00)	.32 [-.09, .73]
Homesickness	-6.64 (7.46)	-6.59 (8.09)	-.04 (3716)	.968 (1.00)	-.02 [-.23, .27]	-6.66 (6.72)	-8.35 (8.55)	1.07 (92)	.287 (1.00)	.22 [-.19, .63]
Resilience	-.02 (.66)	.07 (.77)	-.96 (509)	.335 (1.00)	-.13 [-.38, .11]	-.08 (.65)	.02 (.71)	-.76 (92)	.452 (1.00)	-.16 [-.57, .25]
Self-efficacy	.49 (4.66)	.56 (4.90)	-.12 (568)	.908 (1.00)	-.05 [-.29, .20]	.53 (4.49)	1.20 (3.78)	-.76 (92)	.446 (1.00)	-.16 [-.57, .25]
Mindfulness	.59 (5.57)	1.34 (5.13)	-1.02 (644)	.306 (1.00)	-.14 [-.39, .11]	.58 (4.89)	2.07 (4.88)	-1.46 (92)	.147 (1.00)	-.30 [-.71, .11]

Note: *M* = Mean, SD = Standard deviation. *d* [95% CI *d*] = Cohen's *d* [95% confidence interval of Cohen's *d*]. *p'* = adjusted p-value using the Holm-Bonferroni sequential correction. Bolded values represent the primary analysis.

Table 5.3. provides additional clarity on the changes in mental health outcomes at all three time points, within each condition. Intervention participants reported improvements in the college adjustment subscales negative affect and homesickness, but with worsening positive affect from Time 1 to Time 2 (although in the ITT analyses the improvement in homesickness was not statistically significant following adjustment for multiple testing, p = .013 to p' = .444). Excluding positive affect, these improvements increased and were maintained until Time 3. Further, intervention participants reported additional improvements in distress and mindfulness from Time 1 to Time 3 (although in the ITT analyses these were not statistically significant following adjustment for multiple testing, distress p =.001 to p' =.056; mindfulness p = .008 to p' = .279).

Waitlist control participants also reported a pattern of worsening positive affect prior to receiving access to the app from Time 1 to Time 2. But as with the intervention participants, following the provision of Headspace, waitlist participants reported statistically significant improvements in college adjustment (specifically improvements in negative affect and homesickness) from Time 1 to Time 3. Patterns of improving distress and worsening positive affect were also reported but these were not statistically significant following adjustment for multiple testing. (distress p = .034 to p' =1.00, positive affect p = .021 to p' =. 707).

Table 5.3.

Descriptive statistics and paired t-test results comparing all major outcomes across Time 1 to Time 2, and Time 1 to Time 3 within each condition

	Intention-to-treat							Per Protocol						
	T1	T2	T3	T1 vs T2		T1 vs T3		T1	T2	T3	T1 vs T2		T1 vs T3	
Intervention	*M* (SD)	*M* (SD)	*M* (SD)	*t* (*df*)	*p* (*p'*)	*t* (*df*)	*p* (*p'*)	*M* (SD)	*M* (SD)	*M* (SD)	*t* (*df*)	*p* (*p'*)	*t* (*df*)	*p* (*p'*)
Distress	20.01 (5.42)	21.16 (6.84)	18.26 (3.50)	-1.57 (153)	.119 (1.00)	3.18 (2677)	.001 (.056)	20.26 (5.37)	19.15 (6.28)	17.71 (5.08)	2.04 (90)	.044 (1.00)	3.73 (40)	.001 (.023)
College adjustment	82.19 (16.26)	85.27 (15.77)	93.20 (11.17)	-1.74 (225)	.083 (1.00)	-6.68 (2067)	<.001 (<.001)	81.46 (15.68)	87.11 (17.06)	93.96 (17.67)	-3.53 (90)	.001 (.024)	-4.94 (40)	<.001 (.001)
Positive affect	31.01 (5.00)	28.50 (5.39)	30.64 (3.84)	3.80 (91)	<.001 (.010)	.68 (575)	.497 (1.00)	30.82 (5.17)	29.22 (5.33)	30.80 (5.48)	3.08 (90)	.003 (.092)	.59 (40)	.556 (1.00)
Negative affect	36.10 (10.24)	32.09 (10.05)	29.75 (7.17)	3.51 (245)	.001 (.021)	6.00 (3056)	<.001 (<.001)	36.82 (9.67)	31.30 (10.72)	28.98 (11.02)	5.44 (90)	<.001 (<.001)	5.04 (40)	<.001 (<.001)
Homesickness	24.37 (7.56)	22.05 (7.02)	17.78 (4.94)	2.53 (111)	.013 (.444)	8.75 (2527)	<.001 (<.001)	24.45 (7.31)	21.47 (7.25)	17.87 (7.30)	3.87 (90)	<.001 (.008)	6.25 (40)	<.001 (<.001)
Resilience	3.31 (.74)	3.30 (.74)	3.38 (.55)	.18 (74)	.858 (1.00)	-.96 (1078)	.336 (1.00)	3.30 (.77)	3.35 (.76)	3.40 (.81)	-.84 (90)	.404 (1.00)	-.22 (40)	.826 (1.00)
Self-efficacy	30.29 (4.44)	29.08 (4.61)	30.85 (3.01)	2.06 (88)	.043 (1.00)	-1.19 (644)	.235 (1.00)	30.03 (4.26)	30.07 (4.37)	31.73 (4.05)	-.08 (89)	.936 (1.00)	-2.03 (40)	.049 (1.00)
Mindfulness	30.41 (4.83)	30.92 (4.53)	31.75 (4.06)	-1.02 (370)	.309 (1.00)	-2.67 (509)	.008 (.279)	30.34 (4.77)	31.03 (4.66)	32.12 (5.69)	-1.50 (89)	.138 (1.0(	-2.72 (40)	.010 (.309)
Waitlist Control														
Distress	19.41 (5.51)	21.23 (6.93)	18.22 (4.41)	-3.03 (254)	.003 (.098)	2.12 (851)	.034 (1.00)	19.25 (5.42)	20.06 (6.64)	17.79 (6.09)	-1.72 (103)	.088 (1.00)	2.57 (52)	.047 (1.00)
College adjustment	84.71 (16.31)	83.93 (15.74)	93.59 (12.44)	.56 (791)	.574 (1.00)	-5.70 (2750)	<.001 (<.001)	84.33 (16.20)	84.83 (16.46)	93.98 (17.61)	-.39 (103)	.695 (1.00)	-3.76 (52)	<.001 (.017)
Positive affect	31.94 (5.36)	29.09 (5.38)	30.59 (5.04)	5.28 (456)	<.001 (<.001)	2.30 (2001)	.021 (.707)	32.05 (5.44)	29.68 (5.28)	30.47 (6.87)	4.72 (103)	<.001 (<.001)	2.08 (52)	.043 (1.00)
Negative affect	34.71 (10.78)	33.67 (10.39)	29.85 (8.20)	1.19 (551)	.236 (1.00)	4.64 (2368)	<.001 (<.001)	35.10 (10.80)	33.38 (10.89)	29.91 (11.43)	2.18 (103)	.032 (.917)	3.63 (52)	.001 (.024)
Homesickness	23.96 (7.02)	22.75 (7.04)	17.32 (4.87)	1.71 (338)	.087 (1.00)	9.51 (1443)	<.001 (<.001)	24.13 (6.67)	22.53 (7.23)	16.89 (6.38)	2.60 (103)	.011 (.333)	7.21 (52)	<.001 (<.001)
Resilience	3.43 (.65)	3.35 (.73)	3.41 (.58)	1.27 (133)	.205 (1.00)	.38 (339)	.707 (1.00)	3.44 (.68)	3.40 (.74)	3.43 (.75)	.71 (103)	.479 (1.00)	.91 (52)	.365 (1.00)
Self-efficacy	29.89 (4.68)	29.14 (4.51)	30.38 (3.71)	1.79 (526)	.074 (1.00)	-1.08 (500)	.281 (1.00)	29.97 (4.61)	29.75 (4.35)	30.19 (4.82)	.66 (102)	.513 (1.00)	-.86 (52)	.395 (1.00)
Mindfulness	31.01 (5.19)	30.05 (5.18)	31.60 (4.60)	2.17 (235)	.031 (.995)	-1.09 (479)	.274 (1.00)	31.16 (5.07)	30.00 (5.33)	31.36 (5.99)	3.42 (103)	.001 (.032)	-.87 (52)	.388 (1.00)

Note: *M* = Mean, *SD* = Standard deviation. *p'* adjusted p-value using the Holm-Bonferroni sequential correction.

5.3.3. App use as a predictor of mental health

In Table 5.4. I present a series of multiple regression analyses using dummy coded categorical app use to predict mental health (with baseline mental health as a covariate) for intervention participants at Time 2 (ITT: top rows; PP: bottom rows). No app use (0–3 meditations), was the reference group, which was compared with low use (4–8 meditations across three months), and with moderate use (9+ meditations across three months). When the reference group was recoded I also compared low use to moderate use. For consistency, I repeated these analyses for the waitlist and intervention participants at Time 3; these analyses are available in Supplemental results (Supplemental Table 5.5. and 5.6.).

In intervention participants ITT analyses, moderate app use was associated with a five-point greater reduction in distress and a 10-point greater increase in college adjustment than those reported by non-users at the beginning of semester 2 (Time 2). Improvements in negative affect, homesickness, and self-efficacy were also reported, however, these tests did not retain statistical significance following adjustment for multiple testing. Low use of the app did not confer any notable benefits above non-use. Similar patterns were observed in in PP analyses but a four-point reduction in distress for moderate users compared to low users at Time 2 was the only pattern of app use as a predictor of mental health that retained significance when adjustments were made for multiple testing. At Time 3 (a several month lag since access to the app), moderate users still reported a 1.6-point greater reduction in distress than non-users in addition to a 3-point greater reduction in distress than low users (Supplemental Table 5.6.).

By contrast, moderate app use by waitlist control participants did not yield the same patterns except that moderate app users reported higher mindfulness than low users, but not non-users. Low use was also associated with lower mindfulness scores than the mindfulness of non-users. As previously, this pattern was not statistically significant following adjustment for multiple tests. See Supplemental Table 5.5. for waitlist control models.

Table 5.4.

Mental health and academic outcomes at Time 2 (intention-to-treat: top rows; per protocol: bottom rows) were predicted using intervention participants' objective app use categorically coded into No use (0–3 meditations), Low use (4–8 meditations), and Moderate use (9+ meditations). Time 1 outcomes were controlled in all analyses.

Outcome	(No use) Constant (SE)	Baseline of outcome (SE)	(No use vs.) Low use ß (SE)	Sig (2-tailed)	Sig' (2-tailed)	(No use vs.) Moderate use ß (SE)	Sig (2-tailed)	Sig' (2-tailed)	(Low use) Constant (SE)	(Low use vs.) Moderate use ß (SE)	Sig (2-tailed)	Sig' (2-tailed)	R^2 (R^2 change)
Distress	22.93 (.92)***	.50 (.11)***	-2.27 (1.75)	.194	1.00	-5.37 (1.35)	<.001	<.001	20.66 (1.49)***	-3.10 (1.83)	.090	1.00	.28 (.12)***
College adjustment	81.58 (2.06)***	.42 (.08)***	5.48 (3.98)	.169	1.00	10.87 (3.05)	<.001	<.001	87.05 (3.40)***	5.39 (4.16)	.195	1.00	.28 (.09)**
Positive affect	27.81 (.85)***	.41 (.10)***	1.01 (1.50)	.501	1.00	2.04 (1.17)	.082	1.00	28.82 (1.23)***	1.03 (1.53)	.498	1.00	.20 (.03)
Negative affect	34.13 (1.34)***	.40 (.09)***	-2.78 (2.61)	.288	1.00	-6.14 (2.00)	.002	.092	31.36 (2.23)***	-3.36 (2.74)	.219	1.00	.24 (.07)*
Homesickness	23.39 (1.15)***	.35 (.09)***	-1.66 (1.96)	.396	1.00	-4.10 (1.61)	.012	.528	21.73 (1.59)***	-2.44 (1.96)	.214	1.00	.21 (.07)*
Resilience	3.21 (.10)***	.56 (.09)***	.26 (.18)	.154	1.00	.19 (.14)	.187	1.00	3.48 (.15)***	-.26 (.18)	.154	1.00	.36 (.02)
Self-efficacy	28.26 (.72)***	.41 (.10)***	.67 (1.28)	.601	1.00	2.64 (.96)	.006	.270	28.93 (1.06)***	1.98 (1.29)	.127	1.00	.21 (.06)*
Mindfulness	30.42 (.60)***	.40 (.09)***	.27 (1.18)	.820	1.00	1.68 (.99)	.091	1.00	30.69 (1.01)***	1.41 (1.26)	.264	1.00	.23 (.03)
Distress	19.98 (.82)**	.72 (.11)**	1.05 (1.21)	.393	1.00	-2.95 (1.04)	.010	.440	**21.02 (.96)****	**-4.00 (1.13)**	**.001**	**.048**	**.440 (.064)****
College adjustment	83.49 (2.24)**	.60 (.09)**	2.60 (3.87)	.498	1.00	9.27 (2.97)	.004	.188	86.10 (3.17)**	6.67 (3.76)	.081	1.00	.384 (.060)*
Positive affect	28.70 (.66)**	.56 (.11)**	-.05 (1.30)	.970	1.00	1.54 (1.09)	.160	1.00	28.65 (1.14)**	1.59 (1.35)	.261	1.00	.326 (.019)
Negative affect	33.24 (1.56)**	.60 (.10)**	-1.18 (2.11)	.564	1.00	-5.08 (2.01)	.015	.630	32.06 (1.67)**	-3.90 (2.09)	.068	1.00	.352 (.046)*
Homesickness	22.93 (1.05)**	.48 (.09)**	-.99 (1.76)	.577	1.00	-3.78 (1.37)	.008	.360	21.94 (1.43)**	-2.79 (1.66)	.092	1.00	.297 (.056)*
Resilience	3.26 (.09)**	.69 (.07)**	.20 (.18)	.262	1.00	.15 (.12)	.195	1.00	3.46 (.15)**	-.04 (.17)	.809	1.00	.514 (.013)
Self-efficacy	29.84 (.59)**	.60 (.10)**	-.79 (.80)	.340	1.00	1.13 (.90)	.200	1.00	29.05 (.49)**	1.92 (.81)	.025	1.00	.371 (.026)
Mindfulness	30.29 (.62)**	.56 (.10)**	.35 (.96)	.737	1.00	1.87 (.89)	.038	1.00	30.64 (.67)**	1.52 (.92)	.106	1.00	.360 (.034)

Note: † $p < .10$, * $p < .05$, ** $p < .01$, *** $p < .001$ denotes significance levels where otherwise unspecified.

5.3.4. Demographic and baseline mental health characteristics as post-hoc predictors of app use

There were no significant demographic or baseline mental health differences between conditions in any app use variables with one notable exclusion. Those who were *more* distressed at baseline completed *more* meditation sessions for *more* minutes overall (number of sessions: r .159, p = .012, *n* = 250 minutes meditated: *r* .192, *p* = .002, *n* = 250). But, this relationship appeared to be driven by the waitlist participants (number of sessions: *r* .197, *p* = .027, *n* = 126 [waitlist] vs *r* .123, *p* = .175, *n* = 124 [Intervention]; minutes meditated: *r* .249, *p* = .005, *n* = 126 [waitlist] vs *r* .130, *p* = .149, *n* = 124 [Intervention]).

5.4. Discussion

In the current study, I provided incoming university students with three months of access to Headspace, a mindfulness meditation app, in their first or second semester of university. When comparing the more rigorous ITT primary analysis to PP primary analyses, there was weak evidence for our primary hypothesis (H1) that the intervention would be associated with improvements in psychological distress over time. Beyond the primary analysis, however, I found that access to and use of the mindfulness app was associated with improvements in psychological distress and college adjustment, and some evidence of improved mindfulness. Although the improvements were small to moderate, they were consistent and more apparent in those who used the app more frequently and in those who received the app earlier in the academic year. Further, use of the mindfulness app was higher when intervening early in the academic year. Participants were more likely to initiate using the app when it was provided to them at the start of the year (66.1% vs. 44.4%) and they were more likely to continue practicing beyond the first week when the intervention began in semester 1. Thus, access to and use of a mindfulness app during the first year, and particularly the first semester of university, may help reduce distress and improve adjustment to university life.

5.4.1. Limitations

Two main factors limit the conclusions that can be drawn from this study. First, I used a waitlist control design meaning that although I had controlled for expectation effects, I cannot discount other non-specific intervention factors such as the digital placebo effect (placebo-like effects found in digital interventions that are unrelated to active components of therapy; Torous & Firth, 2016) nor can I demonstrate non-inferiority to established treatments. In other psychotherapeutic interventions, waitlist control designs have been associated with exaggerated intervention effectiveness (e.g., see Furukawa et al., 2014 on waitlisted Cognitive Behavioural Therapy [CBT] for depression). But there are few well-established comparison or control groups for mindfulness interventions. That is, mindfulness-based interventions do not lend themselves well to many control group designs (e.g., placebo or no-treatment controls) because the active and inactive components of the intervention are challenging to identify or dismantle, and no-treatment may be unethical where participants are in distress (Kinser & Robins, 2013). An additional layer of complexity is added when considering appropriate control groups for mind-body interventions delivered using a mobile device. At the time of this trial I was unaware of any acceptable "sham" control options, however, recently Noone and Hogan used an app-based "sham mindfulness" condition where participants did guided breathing exercises that were referred to as meditation but where no guidance was given on how to control their awareness of their body or breath (Noone & Hogan, 2018). In future trials, I would consider comparing the intervention to an active control such as app-based "sham mindfulness" or to an effective and well established CBT app (although to our knowledge, these may not yet exist; Rathbone, Clarry, & Prescott, 2017).

Second, while this study was adequately powered at the start of semesters 1 and 2, the same was not true of the final time point, the end of the academic year. The survey attrition rate from allocation at the end of the academic year was 62.4%. Given we were underpowered to detect effect sizes of $d = .4$ at the final time point, I have used an intention-to-treat approach (by multiply imputing data) and presented these analyses alongside the complete cases per-protocol

analyses. Further I applied a stringent and conservative Holm-Bonferroni adjustment for multiple tests, tempered the strength of our conclusions at the final time point, and limited our conclusions to outcomes that were consistently significant across tests (i.e., distress and college adjustment).

5.4.2. App-based mindfulness meditation, psychological distress, and other mental health outcomes

Although I did not find support for our primary hypothesis (H1) in the ITT analyses, access to a mindfulness app in an incoming university student population was associated with small improvements in psychological distress when compared to a waitlist control in the PP analyses. In both ITT and PP analyses, I found some support for our exploratory hypotheses (H3). That is, I found that following access to the mindfulness app, incoming university students reported improvements in college adjustment that were sustained through to the end of the academic year. Similarly, following access to the app, waitlist participants also reported significant improvements in college adjustment when compared to their baseline levels of college adjustment. Improvements in distress, college adjustment, and mindfulness (PP analyses only) replicate previous research that demonstrated that access to Headspace was associated with improvements in depressive symptoms, college adjustment, and mindfulness (Flett et al., 2019). Unlike previous research, I did not find consistent evidence that app-based mindfulness was associated with changes in resilience nor in self-efficacy (Flett et al., 2019).

5.4.3. Mindfulness app use as a predictor of mental health

I found some support for the hypothesis that there would be a dose-response relationship between app use and improvements in mental health (H2). That is, I found that moderate use of the mindfulness app was associated with significant improvements in distress and college adjustment as compared to no use of the app. But, I also found preliminary evidence that the longer-term nature of the dose-response relationship was not linear. Although these results suggest that moderate use may offer some protective factors against distress, in some examples I

also found that moderate use was more beneficial when compared to low use than compared to no use. I speculate that there might be a minimum dosage threshold before improvements can be experienced. Below this hypothetical threshold, it may be that the dosage is not strong enough or could indicate other issues related to poor follow-through (desire to use the app initially, but inability to persist). I am not alone in finding nonlinear associations between intervention dosage and mental health improvements. For example, in an unguided web-based intervention based on cognitive behavioural therapy and interpersonal therapy for people with depression and cardiovascular disease, high-level use was beneficial, but medium-level use offered little benefit over and above low use (Donkin et al., 2013). Thus, assumptions of a linear dose-response relationship may be too simplistic, and further models and variables need to be explored to adequately understand the association. Although there were no baseline demographic or mental health differences between non-users, low-users, and moderate users in the current study, students who take advantage of mental health resources may differ (in other ways not measured here) from those who do not and these individual differences may help explain later mental health outcomes.

5.4.4. Uptake and timing of app-based mindfulness

Our findings also provide important information on the frequency of app use in an uncontrolled setting. As part of our pragmatic design (Zwarenstein et al., 2008), I took a hands-off approach to encouraging engagement with the intervention (i.e., only six brief SMS text messages over the course of the semester reminding students of their access to the app) and app use was at the discretion of the participant (not mandated nor rewarded). Under the constraints of this design, app use averaged approximately two times per month which is low, but consistent with real-world uptake in digital and self-help apps (Lattie et al., 2016). Given the low app usage, it is notable that I still found an impact on distress and college adjustment. But I also found that higher app use was associated with greater improvement, indicating that increasing app use should be a focus of future research. An overarching goal of intervention implementation is that eventually an intervention should gain independence from the researchers

(Bauer et al., 2015). Given this goal, the next step in this research involves considering how persuasive design and theory-based strategies could be used to increase the impact and usage of app-based mindfulness interventions, while still maintaining a hands-off approach from researchers (Kelders et al., 2012; Morrison, 2015).

There are two main features of the current study related to persuasive design and theory-based strategies that may warrant examination. First, the app-based mindfulness programme used here, Headspace, already includes several persuasive design features which may increase the impact and usage of the app (e.g., Headspace has gamified user tracking, a reminder function, push notifications called 'mindful moments', and the option of sharing your mindfulness statistics with a friend). Although these design features were available to participants, their use was at the discretion of the participants and I do not have objective data on their use. In future research, these persuasive design features could be leveraged to promote app use and encourage habit formation. Second, the intervention setting used here, first-year residential colleges, already includes health and well-being events and tools as part of their standard pastoral care for residents. Although this intervention took place in two first-year residential colleges, it was not embedded within their existing practices. In future research, the first-year residential college setting could be better utilised to increase the impact and use of the app.

Our findings also suggest that the timing of app-intervention delivery is important. Earlier intervention in the first semester was associated with increased uptake (66.1% in first semester vs. 44.4% in second semester) greater adherence (approximately 15 minutes longer within the first four weeks) and greater persistence in practice (continuing use of the app after the first week). The early transition to university may be a more effective time to implement interventions, relative to later in the year (c.f. Riordan & Carey, 2019).

5.4.5. Conclusion

App-based mindfulness training may be a useful tool to improve student distress and adjustment in the first year of university, but further research is required. Students who used the

mindfulness app more frequently reported reductions in distress and improved college adjustment relative to those who did not use the app. Intervening early was associated with greater use of the app and more establishment of app use as a habit, suggesting that interventions might have better uptake earlier in the academic year. Whilst mindfulness apps are not a substitute for clinical treatment in university settings, they may fill a gap where students might not seek help otherwise. App-based mindfulness was associated with modest mental health improvements, and intervening during the transition to university from within residential colleges might provide a window of opportunity to reduce student distress.

5.5 Acknowledgements

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CHAPTER 6: GENERAL DISCUSSION

Concluding thoughts

In the Kālama Sutta from the Pāli Canon, the Buddha is asked the question: "There are so many teachers around, who are we to believe?" He answers: "Do not rely on tradition, scripture, authority, or philosophy. Only when you see for yourself that a practice leads to suffering or to wellbeing then you should reject or accept it."

(Maex, 2011, p.168)

There are many ways to alleviate suffering and no one method is correct; instead any method is correct, provided it alleviates suffering. The quote above, attributed to the Buddha, brings me back to both the goal of this thesis and its primary contribution. In this thesis I set out to investigate the effects of app-based mindfulness meditation on the mental health of university students. Although I began as somewhat sceptical of the impact that brief mindfulness interventions could have and keenly aware of the paradox of using mobile phones to deliver mindfulness meditation, through the research I conducted here, I found that app-based mindfulness meditation was associated with modest mental health benefits in both new and more senior university students. More specifically, in Studies 1 and 3 (in healthy and incoming university students), I found consistent evidence that app-based mindfulness meditation had statistically significant impacts on university students' distress or depressive symptoms, and some evidence of increased mindfulness. Importantly in both of these studies, app-based mindfulness was also associated with improvements in their adjustment to college life – a factor that is believed to influence later university outcomes. In addition to the effects of the app-based mindfulness intervention, I also identified that university students were an at-risk population experiencing relatively high levels of stress and psychological distress, and that the transition to university represents a unique window of opportunity to intervene with them. In Study 2 (in distressed students), I found, yet again, that there is great but unmet mental health needs in the university student population who are seeking mental health services, however, an app-based mindfulness program may not be the tool these students need

(or at least not in the way it was provided here). Overall, this body of work contributes to the growing research on the effectiveness of mindfulness meditation as a therapeutic intervention in both clinical and non-clinical populations. It also adds to the growing body of evidence supporting digital and web-based interventions as a viable and acceptable means of intervening with adults.

In this final chapter, I briefly review the main contributions of this body of work. I then overview the strengths and weaknesses of this research before making a few suggestions for further avenues of research.

6.1. Contributions of this research

In Chapter 1, I reviewed the existing mindfulness research to demonstrate that small to moderate effects on mental health outcomes could be expected of mindfulness-based interventions. In this review I also highlighted many of the limitations of the conclusions being drawn from this research. These limitations included the reliance on small and underpowered samples and the use of waitlist and no-treatment controls. More specific to app-based mindfulness research, the limitations included brief interventions (primarily interventions lasting less than two weeks), short follow up times, and a lack of external validity. These methodological limitations, and the additional justifications provided in Chapter 2, provided the rationale for Study 1.

The main contribution of Study 1 (Chapter 3) was the preliminary evidence that app-based mindfulness had effects on mental health outcomes, but also that it is important to consider app-specific effects. Here, I trialled two mindfulness meditation apps that both provided introductory mindfulness meditation training. Despite both apps offering introductory mindfulness training, only Headspace users reported an increase in mindfulness meditation. Although the lack of improved mindfulness in Smiling Mind users was contrary to logic (i.e., that an MBI should result in increased mindfulness), this finding was consistent with previous research. That is, in a systematic review of group-based MBIs, only

approximately half of all interventions were associated with improved mindfulness (Visted, Vøllestad, Nielsen, & Nielsen, 2015). It is possible that these inconsistencies may reflect measurement error in light of the ongoing discussion around the challenges of measuring mindfulness.

In Study 1 (Chapter 3) a more challenging finding to reconcile was that although both mindfulness apps were initially associated with improved mental health, when controlling for participants' tendency to want to grow or change as a person, the effects of the *Smiling Mind* dropped off in a post-hoc exploratory analysis. It was unclear why there would be differences between two apps that were delivering ostensibly the same active intervention components, but participant feedback during ongoing focus groups revealed that one of the apps - Smiling Mind - was clunky, cumbersome, and buggy. Smiling Mind users indicated that it was a challenge to get into the mindfulness zone when using the app because of technical difficulties associated with the app, not because of difficulties associated with the content of the training. By contrast, users of Headspace reported that it was easy to use and aesthetically pleasing. Consistent with earlier research, the more user-friendly Headspace was associated with improvements in mental health outcomes, even after controlling for participants' tendency to want to grow or change as a person. A finding unique to this thesis was that app-based mindfulness may have implications for the degree to which students adjust to college life. Improvements in mental health and college adjustment served as the rationale for targeted interventions using Headspace with specific student populations in Studies 2 and 3.

Another contribution stemming from Study 1 was relegated to the Supplementary material but still makes a substantive contribution. As a sub-study, I replicated Study 1's design comparing app-based mindfulness (Headspace) to email-based mindfulness (the 10 Minute Mind) and to the attention control used in Study 1. In this study I demonstrated that self-reported adherence is not an effective way to measure objective adherence for app-based interventions (but was sufficient for email-based interventions). This study served as the rationale to abandon self-reported adherence in Studies 2 and 3.

The main contribution of Study 2 (Chapter 4) was demonstrating the many challenges associated with implementing digital mental health interventions in real-world settings, e.g., in a student health service. In Study 2, I identified that there is serious unmet need in the mental health of university students who are waiting for services. More specifically, the functional impairment of this sample of students was so high that on average they reported being unable to function at all for one week of the past month and had reduced ability to function for 10 days of the past month. Ultimately, I found that Headspace might not be the solution for these students, but that they certainly need a solution.

The main contribution of Study 3 (Chapter 5) was identifying that the transition to university is not only a time of great stress for students but also that it is the optimal time to intervene. That is, intervening during the transition at the beginning of the academic year had stronger effects on student mental health than intervening later in the year. App-based interventions were acceptable to students on a global scale, but not widely used. Even so, consistent with Study 1, their use was beneficial effects of app-based mindfulness, especially in terms of rates of distress and increasing the adjustment to college life.

Taken together, the primary application of this work is that although app-based mindfulness should not be a replacement for existing effective mental health treatment approaches, app-based mindfulness may be suitable for the maintenance of mental well-being in stressed but otherwise healthy student populations. The findings from the current thesis also demonstrate that as little as 10 minutes of mindfulness per day for 10 days translates into statistically significant mental health gains, and that with continued practice, these changes can be maintained at least in the short to medium term. Of course, statistical significance should not be confused with practical and clinical significance. In both Study 1 and Study 3, Headspace was associated with only modest improvements in depressive symptoms (Study 1), mindfulness and college adjustment (both) ranging from of g = .2 to .3. This effect size was consistent with Goyal et al.'s (2014) meta-analysis of 47 MBIs, which the authors noted was ‘comparable with what would be expected from the use of an antidepressant in a primary care

population but without the associated toxicities' (p. 364). To further demonstrate the clinical significance of these modest effects, an effect size of .2 to .3 means 11 to 17 students need to receive Headspace in order for one student to improve (using the Numbers-Needed-to-Treat calculator provided by Magnusson, 2014 where 20% of the control group is assumed to improve). Put another way, if 100 students were to receive Headspace, between 6 and 10 students would be expected to improve compared to if they had received the control treatment. This rate of improvement is slightly lower than other app-based interventions for depressive symptoms (see: Firth et al., 2017). The practical significance of these modest effects should also be considered against the backdrop of the cost-effectiveness, ease of implementation, and ability to reach a wide sample.

6.2. Limitations of this thesis

As with all research, there were several limitations of the research presented in this thesis. First, the problem of comparison groups was a challenge here, much in the same way that it has challenged previous mindfulness research. In Study 1, for example, I replicated an attention control previously used in Howells, Ivtzan, and Eiroa-Orosa (2016). I modified this control condition by telling participants it was an active condition. Despite being pitched as an active condition, this control condition was not perceived to be as effective as Headspace and although it was not formally recorded as part of the study it is likely that participants realised they were in the control condition. Thus, in Study 1, the control condition can be best characterised as an attention control (i.e., controlling for time with researcher and time spent on the intervention – an active non-specific control) but not as an attention-placebo control (i.e., controlling for the addition of participant expectation).

In Studies 2 and 3 I had to rely on waitlist controls as a comparison group. The use of waitlist comparisons is one of the most oft-cited limitations of previous mindfulness research. And, rightly so. The dangers of relying on waitlists are most adequately demonstrated when looking at an example outside of app-based mindfulness research. In network meta-analysis on

CBT interventions for depression (a well-established treatment option), waitlist control designs were associated with exaggerated intervention effectiveness higher than that found in no-treatment controls (Furukawa et al., 2014). Furthermore, reflecting ongoing concerns about digital placebos (Torous & Firth, 2016), a recent meta-analysis looking at the efficacy of app-based mental health interventions[43], revealed that studies using waitlist controls reported intervention effect sizes for depression and anxiety that were approximately g = .20 higher than studies using attention or placebo controls (Linardon, Cuijpers, Carlbring, Messer, & Fuller-Tyszkiewicz, 2019). In both of the studies included in this thesis, there were unique constraints that did not permit an alternative control condition. The first constraint was that the management in both Student Health Services and the Residential Colleges were uncomfortable with the idea of a placebo or inactive interventions. The second constraint was that more broadly it is challenging to find an adequate control group that is both digital and comparable to mindfulness. At the time of conducting these trials there were no rigorous or evidence-based specific-active control alternatives (i.e., there were no evidence-based CBT apps). As a silver lining, the use of a waitlist in both studies did provide us with the opportunity to answer important questions about the timing of the interventions. That is, the transition to university is a unique and effective time period to intervene in student populations (as demonstrated here, in Study 3, but also elsewhere e.g., Riordan & Carey, 2019). Likewise, the question of intervention timing in the provision of services at Student Health Services would have been uniquely informative, had the intervention been successfully implemented.

Although there were no acceptable app-based alternative controls during the data collection for these studies, alternatives are beginning to become available and I speculate that I may have had a hand in that. After conducting Study 1, I was able to negotiate a research agreement with Headspace wherein Headspace would provide free access to their app and to participants use data (with participants' consent). When discussing the limitations of my own

[43] Note that the peer-reviewed manuscript presented in Study 1 was one of the 66 studies included in (Linardon, Cuijpers, Carlbring, Messer, and Fuller-Tyszkiewicz's (2019) meta-analysis. Further, studies using informational resources were even more biased in favour of the intervention (g = .39 when informational, vs. g = .12 when attention/placebo control).

research (e.g., Study 1) and the broader limitations of mindfulness research with my contact at Headspace (former research scientist, Brad Sanderson), I made several suggestions about more acceptable control conditions. Specifically, I suggested that an equivalent sham meditation app would have strong scientific value. I cannot be certain that my suggestions spurned this action, however, Headspace subsequently created a sham meditation app that was used in a recent study (Noone & Hogan, 2018). Unfortunately, given the widely publicized finding that Headspace conferred no advantage over sham Headspace (voice-and time-matched breathing exercises with no guidance relating to awareness of their body or breath), I speculate that it may be unlikely for this sham meditation app to be available to other researchers due, at least in part, to the fact that it may threaten Headspace's bottom line. Even so, Noone and Hogan's (2018) work demonstrates an interesting point, it may be that the expectancy of receiving mindfulness, but not mindfulness itself, is related to improvements. With this in mind, future researchers should consider dismantling trials to better identify the active components (if any) that mindfulness and particularly app-based mindfulness offer. This work is beginning to take place, e.g., Lindsay, Young, Brown, Smyth, and Creswell (2019) and Lindsay, Young, Smyth, Brown, and Creswell (2018).

Second, in each of these studies, I implemented only a brief mindfulness intervention in terms of both individual sessions (i.e., 10-30-minute guided meditations) and in terms of intervention availability (i.e., access to Headspace for 30-90days). Such brief interventions can have substantive impacts on mental health as demonstrated more broadly in existing psychotherapeutic literature focusing of youth populations (e.g., Bennett et al., 2019; Öst & Ollendick, 2017; Schleider & Weisz, 2017), however, to gain longer term benefits from mindfulness meditation it is important to investigate longer-term app-based practice. Longer-term practice was not the goal of the present research; here I wanted simply to provide people with the means and then see what they do. Do they decide to use it? In the most part, no, but even with such low usership there were still group-level impacts on mental health. Given the

significant moderation effects demonstrated in Study 1, I provide further evidence of the potency that even a little bit of mindfulness can have on mental health outcomes.

6.3. Directions for future research

One key direction of future research should be to identify implementation strategies that promote the adoption and integration of app-based mindfulness into daily life or into specific settings (e.g., mental health care settings). *Implementation science* is a branch of scientific methodology that addresses the barriers and challenges to intervention uptake as an intervention moves from a research-based setting to the intended real-world or clinical setting (Bauer, Damschroder, Hagedorn, Smith, & Kilbourne., 2015). Bridging the research-to-practice gap by prioritising implementation is especially pertinent given that about half of all evidence-based practices do not reach widespread use and on average there is a 17-year lag between evidence-based research and uptake in clinical settings (Balas & Boren., 2000). Implementation studies focus on how to increase the *use* of an evidence-based practice by both clinicians (i.e., providing it to their patients) and patients rather than the effect of the practice on the desired outcome (Bauer et al., 2015). Identifying and removing barriers to implementation improves the overall quality and effectiveness of an intervention and as a result, fewer resources are wasted (what I term "more bang for your buck" in relation to intervention expenditure; Bauer, Damschroder, Hagedorn, Smith, & Kilbourne, 2015; Cristea & Florian, 2019). Hybrid designs that prioritise both implementation (increasing use) and effectiveness (impact of intervention on outcomes) are the next logical step for app-based mindfulness research and indeed any digital health research (because of the constraints of the gold-standard RCT efficacy design, c.f., Mohr, Lyon, Lattie, Reddy, & Schueller, 2017).

Qualitative methods are suited to identifying implementation barriers. Quantitative data from complex interventions typically reflect the aims of the research proposal (that is, 'how you question, forms the answer', Schwarz 1999), rather than what was delivered in practice. To maximise the impact of randomised, controlled trials I believe it is important to

incorporate qualitative research to provide a richer data set. Incorporating qualitative methods that are heavy on participant interaction can clarify issues around the provision of an intervention that may have otherwise been overlooked in the quantitative data (Barbour, 2005). Focus groups can help determine individuals' beliefs about the effectiveness of an approach and can aid the ongoing adaptation of intervention design (and evaluation of interventions) in preparation for future research trials (an example of 'evidence-based planning', O'Cathain et al., 2015). Focus groups and interviews also provide rich descriptive accounts of how the intervention was delivered in practice as told by the perspectives of those on the receiving end of the intervention (e.g., participants or users) and from the perspective of those delivering the intervention (e.g., clinicians). For these reasons, focus groups or semi-structured interviews are often employed as part of a mixed methods approach alongside quantitative research trials. In line with this suggestion, I have begun conducting qualitative implementation research that follows from the studies presented in this thesis. More specifically, I have conducted a series of focus groups with participants in Study 1 and a series of semi-structured interviews with participants from Study 3. I had intended to conduct a focus group with the Counselling Service's clinicians, however, this was no longer appropriate following their service review. Although these projects are ongoing, the addition of qualitative implementation research will further contribute to the growing body of research that is helping to make mindfulness interventions more effective and sustainable outside of strict research conditions.

A related direction of future research is to consider how in-built app features impact app use (or adherence, when the intervention is based in a clinical setting). Large-scale, real-world, user data indicate that only 10% of mindfulness app users are still using their app after 7 days and almost one-quarter of mindfulness app users only use the app on the first day of download (Baumel, Muench, Edan, & Kane, 2019). Even if there isn't a linear dose-response relation between the use of Headspace and psychological outcomes, it is undoubtable that more than one session of mindfulness is required to reap benefits that last beyond the immediate term (see: Schumer, Lindsay, & Creswell, 2018). Using real-world data from 30

web-based behavioural interventions, Baumel and Yom-Tov (2018) found that *Therapeutic Persuasiveness* (the use of persuasive design and behaviour change principles in the web-based interventions) was the strongest predictor of adherence in terms of both duration of use and number of sessions completed. Therapeutic persuasiveness explained 42% of the variance in user adherence (Baumel & Yom-Tov, 2018). Thus, future app-based mindfulness research should focus on identifying therapeutically persuasive app-features that increase adherence or user engagement. Headspace already has a number of in-built features that may fit the bill. For instance, Headspace has push notifications called *Mindful Moments* which send users gentle reminders to be mindful; see Figure 6.1. for examples. Headspace also has a reminder function that participants can adapt to suit their own schedules. These features could be considered persuasive design elements because they encourage use of the app, but they could also possibly be classified as a light touch ecological momentary intervention because they are delivered in everyday life in everyday settings and provide information relevant to increasing mindfulness (Heron & Smyth, 2010). Although I encouraged but did not enforce the use of mindful moments and the reminder function in the current studies, future researchers should consider manipulating the use of these features to see how they affect app use overall and on a daily level.

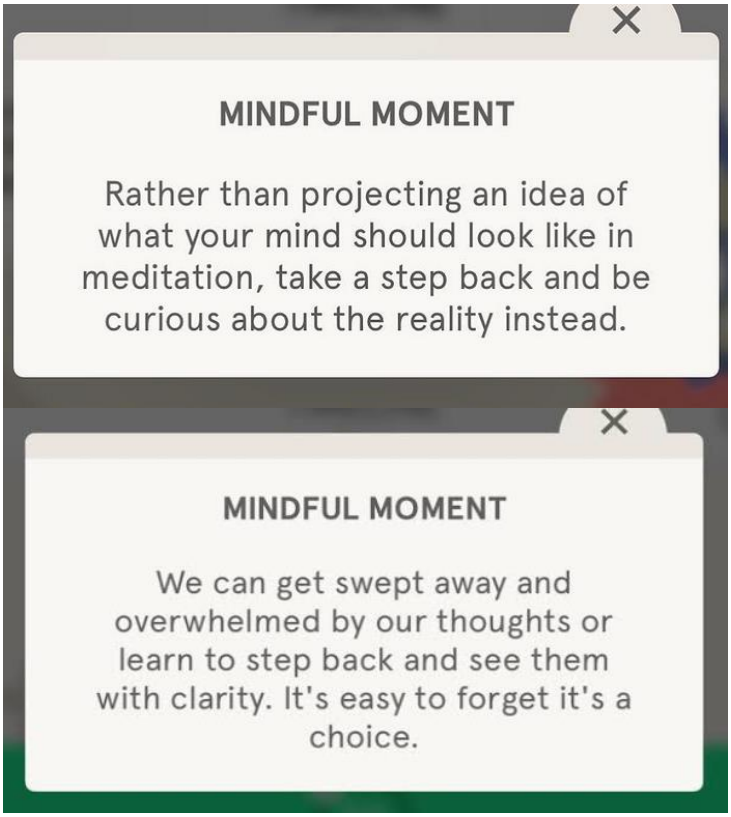

Figure 6.1. **Examples of Headspace app's 'Mindful Moments' push notifications.**

To build on this idea, some UX (user-experience) commentators have noted that Headspace incorporates gamification in order to encourage and maintain app use (e.g., Haisfield, 2018). Gamification is the use of game design and features in non-games and it overlaps with persuasive design (Cugelman, 2013). Some examples of gamification in Headspace include the ability to roam and explore content, using levels and incremental challenges, showing users progress over time, providing badges for achievements, and allowing social sharing.

Looking slightly further abroad, interventions sometimes take the form of games. Persuasive games – games designed to change a player's real-life behaviour or attitude – have been used to change diet, exercise, smoking, and risky sexual behaviours (for examples, see: Orji, Orji, Oyibo, & Ajah, 2018). Recently, work has begun to investigate the impact of player typology on the effectiveness of persuasive games (Orji et al., 2018). Orji et al. (2018) used

the BrainHex player typology (Nacke, Bateman, & Mandryk, 2011) which classifies player's into seven categories:

> *Achiever* - goal oriented and motivated by the reward of long-term goals; satisfied by completing tasks and collecting things.
> *Conqueror* - challenge-oriented, satisfied by beating others at challenging tasks.
> *Daredevil* - satisfied by risk and fast-paced action.
> *Mastermind* - satisfied by solving puzzles and efficient decision making.
> *Seeker* – satisfied by exploring new things, curious, and maintains sustained interest in games.
> *Socializer* – satisfied by interaction with others.
> *Survivor* – satisfied with escape narratives.

Orji et al.'s (2018) findings suggested that player typology may have an impact on the effectiveness of digital health interventions. In their study they found that player typology moderated the effectiveness of persuasive tactics informed by the Health Behaviour Model[44] (a popular health behaviour change theory used to design health interventions; Rosenstock, 2005). Orji et al. (2018) found that achiever's were motivated by perceived susceptibility (what they stood to lose), whereas daredevil's were motivated by perceived benefit (what they stood to gain). Importantly, using an inappropriate persuasive tactic for a particular player-type was be detrimental to health behaviour change. But across all player types, self-efficacy was the most effective persuasive tactic. If persuasive tactics of these interventions work differently for different types of players, the same may be true for the persuasive gamification elements used in Headspace. As far as I am aware, there is no research addressing this particular question, however, the idea that digital mental health tools do not come in 'one-size-fits-all' is a topic gaining traction (e.g., Fleming et al., 2019). Identifying the particular gamification tactics that are effective motivators for different types of users (or 'players') provides an opportunity to better understand how to encourage adherence and create sustainability of use of these digital mental health interventions.

[44] The Health Behaviour Model includes the following facets: perceived susceptibility, perceived severity, perceived benefit, perceived barrier, cues to action, and self-efficacy.

A final direction for future research is to look more broadly at the state of student mental health and the ways to address what some are calling the 'mental health crisis' (e.g., Xiao et al., 2017). Some research suggests psychological distress is higher in students than non-students (e.g., Stallman, 2010), but the evidence is mixed (e.g., Blanco et al., 2008). Even so, most researchers agree that psychological distress is on the rise, especially in young people in Aotearoa New Zealand (Kvalsvig & Health Promotion Agency, 2018; Ministry of Health, New Zealand, 2018). While the issue of student and young adult mental health is undoubtedly multi-factorial and warrants the focus of an entire thesis, social isolation and loneliness is a key area of intervention unanswered in this thesis. In population-level data collected by the Health Promotion Agency, over half of all young people (15-24 years; n = 414) reported they felt isolated in the past 4 weeks. Feeling isolated and that the things they did were not worthwhile (17%) was associated with a seven-fold increase in the likelihood of moderately severe to severe levels of depression relative to their peers. Likewise, those who reported feeling isolated and that they could not cope with everyday stress (15%) were 16 times more likely to report moderately severe or severe depression than their peers. Finally, one in 10 young New Zealanders reported that they would be better off dead or thought about hurting themselves (question 9 in the PHQ-9; Kroenke, Spitzer, & Williams, 2001); if they reported they were isolated or that they did not feel worthwhile those rates rose to 1 in 3. Concerningly, robust research from the USA suggests that response to that particular PHQ-9 question is a strong predictor of subsequent suicide attempt or death (N = 1.2 million; Simon et al., 2016). Although young people are more likely to use social media, they also reported that if they felt depressed they would first turn to friends or whānau rather than online sources of support (Kvalsvig & Health Promotion Agency, 2018). Clearly, the best intervention is to create an environment that fosters social fulfilment, resilience, and well-being. Providing pastoral care is one of the many hats that universities are increasingly required to wear. Beyond the scope of simply educating students, universities and student unions have begun to incorporate resilience and well-being initiatives into their education provision (for example, see the University of Otago's Healthy Campus tools: https://www.otago.ac.nz/healthy-campus/index.html) as well

as events to promote social engagement. Although I did not measure the impact of mindfulness on loneliness, some evidence suggests that the interaction between mindfulness may reduce the negative impact of loneliness on academic achievement in the first year of university (Rosenstreich & Margalit, 2015). In Study 1, I demonstrated that use of a mindfulness meditation app modestly increased resilience and college adjustment while also reducing depressive symptoms, stress, and anxiety. In Study 3, I demonstrated that use of a mindfulness meditation app during the transition to university modestly increased college adjustment and decreased psychological distress. Taking these findings together, I would suggest that although mindfulness meditation is only one of many options available to young people and students, it may serve well as both a preventive and minor interventive treatment.

6.4. Conclusion

In this thesis I present early evidence that use of Headspace, a mobile mindfulness app, can improve some mental health outcomes in a non-clinical population. Across two of the three studies presented here, in addition to several further studies that informed this thesis, I found evidence that app-based mindfulness meditation can have statistically significant impacts on university students' mental health outcomes including distress, depressive symptoms, anxiety, stress, and some evidence of increased mindfulness and resilience. Importantly in both of these studies, app-based mindfulness was also associated with improvements in the adjustment to college life, a factor implicated in later university outcomes. In addition to the effects of the app-based mindfulness intervention, I identified that university students were an at-risk population experiencing high levels of stress and psychological distress. While we cannot take these findings to mean that a single app is a solution to the mental health crisis—nor do I suggest that they should replace traditional face-to-face mindfulness programs—I do think that apps represent promising mobile tools for improving mental health given their 'light touch', ease of use, availability, and accessibility. Importantly, these tools are only effective if people use them. Future researchers should

continue to test the effectiveness of mobile mindfulness apps and to investigate the factors that relate to sustained app usage. Recalling that in 2014, “how to meditate” was the second highest ‘how to’ Google search term in Aotearoa New Zealand, from 2015 through to 2019 in this thesis I have demonstrated that one of the ways to begin your mindfulness meditation practice is to simply grab your phone from your pocket, download an app, and take a deep breath.

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CHAPTER 1: SUPPLEMENTS

Supplements for Chapter 1 include:

S 1.1. Brief mindfulness exercises

S 1.2. Proposed (nonexhaustive) list of study design features of MBI as recommended by Van Dam et al. (2017) and whether these features are reported in this thesis.

Supplement 1.1. Brief Mindfulness Exercises

The following examples are copyrighted by Kent Smith and Janine Hills (contact: kentsmith1@bigpond.com) but are available for personal use on Living Well (retrieved from: livingwell.org.au/mindfulness-exercises-3/ on May 23, 2019).

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Body Scan (https://www.livingwell.org.au/mindfulness-exercises-3/6-body-scan/)

The purpose of this body scan mindfulness exercise is simply to notice your body. It is not necessarily about relaxing your body, however this may occur as a kind of side effect. It is simply about being aware of your body, in this present moment.
Usually, our response to bodily pain or discomfort is to distract ourselves or to try and numb the pain. In this exercise you will accept and notice with gentle curiosity your body in its comfort and discomfort.
Sit or lie down in a comfortable position, making sure that you do not have any constriction. Loosen any tight clothing.
Starting with your feet, pay attention to the physical feelings in them: any pain, discomfort, coolness, warmth, tension, tightness, whatever. Simply pay attention to the physical feelings and sensations. Don't judge them as good or bad, don't try to change them, just be aware of them.
Slowly allow your awareness to drift up from your feet to your lower legs, again simply paying attention to any physical sensations in that part of your body, including any tightness, pain or discomfort. Then slowly let your awareness drift further up your body, doing the same gentle noticing for all of the parts of your body – your upper legs, hips, buttocks, pelvic region, stomach, chest, your lower back, upper back, fingers and hands, lower arms, upper arms, shoulders, neck, your head, forehead, temples, face – eyes, cheeks, nose, mouth, jaw line.
Then let your awareness drift gently and slowly back down your body, noticing any other places where there is pain, discomfort or tension and simply noticing this, until you awareness settles back at your feet.
Commence doing this exercise just for 5 minutes. It can be done sitting down in a chair or lying in bed. Over time, don't worry about how long it takes – just allow yourself to pay attention to the sensations in your body. If, while doing this exercise, thoughts intrude, that's okay – just notice the thoughts, notice yourself noticing the thoughts and gently guide your awareness back to your body.
Note: One variation on this is to focus on parts of your body that you don't like – do this in front of a mirror, noticing your thoughts & feelings as you do the exercise.

Sitting Meditation (Breathing Mindfulness: https://www.livingwell.org.au/mindfulness-exercises-3/5-breathing-mindfulness/)

The purpose of this exercise is to simply notice, accept and be aware of your breath – it is not about relaxation or stress reduction, although this may well occur. Breathing is something we all do – if you have a pulse then you breathe. Your body knows how to do this; it has done it since birth. This is simply about breathing mindfully. Breathing is something you carry with you everywhere; you are just not usually aware of it.
Sit quietly in a chair with both feet on the ground and your hands in your lap. Allow yourself to feel centred in the chair. Bring all of your attention to the physical act of breathing. Start to notice the breath as it enters your body through your nose and travels to your lungs. Notice with curiosity whether the inward and outward breaths are cool or warm, and notice where the breath travels as it enters and departs.
Also notice the breath as your lungs relax and you inhale through your nose. Don't try to do anything with your breathing – simply notice it, pay attention to it and be aware of it. It doesn't

matter if your breathing is slow or fast, deep or shallow; it just is what it is. Allow your body to do what it does naturally.
You will start to notice that each time you breathe in, your diaphragm or stomach will expand… and each time you breathe out your diaphragm or stomach will relax. Again, don't try to do anything – just be aware of the physical sensations of breathing in and breathing out. If you find that thoughts intrude, this is okay. Don't worry, just notice the thoughts, allow them to be, and gently bring your awareness back to your breath.
Start this exercise initially for 5 minutes, building up daily. You can also do this exercise lying down in bed if you have difficulty sleeping. It is simply a way of allowing you to have more mindful and conscious awareness of your body and its surroundings, its breathing and its capacity to relax. When our breathing relaxes our muscles relax.

Loving Kindness and Compassion meditations (Self-compassion mindfulness: https://www.livingwell.org.au/mindfulness-exercises-3/10-compassion-mindfulness/)

In Sanskrit there is a word: *metta*. It doesn't have an exact translation in English. The closest we have is the idea of compassion or loving-kindness – it is that sense of deep and abiding care that you can feel towards another human being; a sense that you wish no harm to come to that person and a feeling of holding them in kindness and care. Sometimes it is possible to get a sense of that feeling by imaging how a parent may feel towards their child. This is an exercise in feeling compassion towards yourself. Self compassion often doesn't come naturally – it is a skill you need to learn, practice and consciously engage in.
Now, allow yourself to notice your breath. Don't feel that you have to do anything to your breathing – just be aware, curious and attentive to the physical sensations of breathing in and breathing out.
Allow yourself now to bring your awareness and attention to that feeling of compassion, loving-kindness or deep and abiding care and concern. Bring to mind someone in your life who is dear and precious to you. Imagine yourself enfolding this person in that feeling. Allow yourself to have the following thoughts towards this person:
May this person know a decrease in distress.
May this person know peace and tranquillity – at least for a while.
May this person know happiness and joy – at least for a while.
May this person be able to deal with their suffering.
Continue to imagine this person, holding them in your mind and sending to the image you hold these loving, kind and compassionate thoughts. Notice how this feels in your body.
What are the physical sensations that come to you when you connect with feelings of loving-kindness and compassion? What are the images and thoughts that come? Just notice these thoughts, physical sensations and emotions – note them with gentle curiosity, without judgement.
Now, if you can, see whether you can direct some of that loving-kindess, compassion and deep abiding care towards yourself. See whether you can have the following thoughts for yourself:
May I know a decrease in distress.
May I know some peace and tranquillity in my life – at least for a while.
May I know some happiness and joy – at least for a while.
May I be confident that I can deal with my own suffering.
Now bring your attention, mindfulness and awareness back to your breath. Notice your inward and outward breath for a few moments.

Noting

Here I provide two examples, one directed at thoughts and one directed at thoughts, sensations, and emotions.

Mindfulness of Thoughts (https://www.livingwell.org.au/mindfulness-exercises-3/8-mindfulness-of-thoughts/)

We often treat thoughts as if they were facts. You may have the thought "I am no good at this," or "He's is a jerk," or "Nobody understand me," or even "I am brilliant!" Does thinking it make it so?
When we have a thought many times, over and over, it can condense into a belief. So a belief is a thought, or a number of connected thoughts, that we have a lot of the time. Beliefs are then quite often taken as facts.
For example: "The world is flat." Enough people had that thought, or held the assumption, often enough for it to be assumed to be a fact for centuries!
When we start to pay attention to our thoughts, with a gentle curiosity, then we start to think about our thinking. We can then move away from believing that the thought is a fact.
Then there's this: If the thought does have evidence pointing to it being a fact, ask yourself a different question. "What does buying into this thought do to me? Does it help? Is it working?"
If the answer is no, then simply move on from the thought. Choose not to get caught up in it.
Start this activity with mindfulness of the breath. Allow yourself to notice any thoughts that come into your head as you are aware of your breathing. Notice, pay attention to and accept these thoughts, without judgement. Thoughts are not bad or good, positive or negative, they just are what they are – the thought that you happen to be having at this particular moment.
You may become aware that you are having difficulty thinking about your thoughts – so think about that. You may be thinking: "I can't do this very well." Well, that's a thought too. Allow yourself to think about that.
Some people like the metaphor of allowing the thoughts to just float like leaves on a stream, or clouds in a sky, noticing each passing thought and then the one that comes after it, and then the one that comes after that. A Buddhist idea is to think of thoughts as pages written on water.
You may notice that just at the moment you become aware of a thought, it passes and is replaced by another thought. That's what happens – thoughts come, and they go.
Finally, bring yourself back to awareness of the breath.

Thoughts sensations and emotions (https://www.livingwell.org.au/mindfulness-exercises-3/9-thoughts-sensations-and-emotions/)

Feelings are often labelled as positive (happy, confident, joyful, brave, etc) or negative (sad, scared, hurt, angry etc). In mindfulness practice, feelings are not good or bad; they just are what they are – emotions that might be comfortable or uncomfortable, easy or difficult. We are often taught to feel that the experience of some feelings is wrong – "You mustn't feel like that," "Be positive," "Don't be sad/scared/hurt" – and that the experience of some feelings is right – "Be happy/brave," "Lighten up," "Move on, get over it." This exercise is simply about noticing whatever you are feeling, at the moment you are feeling it, with a gentle, non-judgemental acceptance and curiosity.
Start off this exercise by becoming mindful of your breath.
Allow yourself now to notice any emotions or feelings you are experiencing. If names for these emotions come that is fine – if they don't, just be aware of them vaguely.
Notice where they are located in your body – your head, throat, chest, stomach, abdomen, gut?
Notice if the physical sensation moves, drifts or shifts.
Notice what they make you feel like – nauseous, queasy, calm, relaxed, tense?
Notice any thoughts that come with the emotions – be aware of them just as thoughts, curiously and without judgment.
Allow yourself to just sit with and notice with awareness the shifting and movement of thoughts, feelings and physical sensations in your body.
Finally, bring your awareness back to your breath for a couple of minutes.

Walking meditation (https://www.livingwell.org.au/mindfulness-exercises-3/4-walking-mindfulness/)

An exercise for practising mindfulness of walking. Before you start, prepare the space. Removing your shoes is good, if that's possible. And find a place where you can walk for about 12-14 steps before you have to turn.
Before you start, prepare the space. Removing your shoes is good, if that's possible. Find a place where you can walk for about 12-14 steps before you have to turn.
Now first notice your body as you stand in stillness. Feeling the connection of the body to the ground, or the floor. Becoming aware of your surroundings, taking in any sights, smells, tastes, sounds or other sensations. Notice any thoughts or emotions and let them be. Notice your arms by your sides or if you prefer, hold your right hand in your left hand at the front, or clasp your hands at your back. Notice your breath, moving in and out of your body. No need to change it; just let it be.
Now shift your weight to the left leg and begin to lift your right foot up. Move it forward, place it back down on the ground. Mindfully shift the weight the right leg and begin to lift the left foot up, move it forward, place it back down on the ground.
And continue with this walking… walking mindfully, walking slowly, and paying attention to the sensations on the soles of your feet. As each part of the sole, from heel to toe, touches the ground. Lifting, moving, placing. Lifting, moving, placing. Notice how the body moves as you walk. Walk with awareness. One step at a time.
When it is time to turn, maintain the flow of mindfulness and bring your awareness to the intricate process of turning. Slowly, and with attention to each movement necessary to turn, begin to walk back to where you started. One step at a time. Lifting, moving, placing. Lifting, moving, placing.
Find a rhythm that suits you. That suits your body and your balance. As you move forward, notice your body, notice your head sitting on your shoulders, your arms & hands, your torso, your legs, moving you forward, step by step.
Notice any thoughts that arise and let them be. Returning your focus to the sensation of walking. Lifting, moving, placing. Notice your breath. Has it moved into a rhythm; a rhythm that fits with your pace of walking, step by step? There's no need to change your breathing, but you might find that it has changed without you noticing it.
Continue walking, taking care to notice each intricate movement required at the turns. One step at a time. Practice this for a moment.
And next time you return to your starting place, be still. Notice the sensations in your body; bring awareness to your breath. Notice the stillness when movement ceases. And appreciate the time you have spent today, practising mindfulness of walking.

Mindful eating (https://www.livingwell.org.au/mindfulness-exercises-3/3-eating-mindfulness/)

An exercise for practising eating mindfulness, or mindfulness of eating. You can practise this exercise with one simple sultana or raisin, a piece of chocolate or a selection of fruit or biscuits on a plate.
Before you choose what you will be eating, come to a place of mindfulness: Sense what your body needs. Notice whether saliva production increases as you look at the platter. Take your time to choose one thing.
Focus with clear awareness on each movement and each moment of the experience as you move your arm and hand and fingers towards the object and pick it up, place it on the palm of your hand or hold it between your fingers.
Imagine you have just come to Earth and awakened to this substance you have not encountered before. Explore it with all your senses as if you have never seen it before. Scan it; explore every part of it with your eyes as it sits on your palm or in your fingers. Turn it around.

Notice the texture, the light on it, its shape; whether it is soft, hard, coarse, smooth. Notice any thoughts that arise (like "why am I doing this?") and see if you can just notice the thoughts and let them be… before bringing your awareness back to the object.
Take the object beneath your nose and carefully notice the smell of it. Bring the object to one ear and squeeze it, roll it, listen for any sound coming from it. Begin to slowly bring the object to your mouth, noticing that the arm knows exactly where to go and perhaps noticing your mouth watering. Gently place the object in your mouth, or take one bite if it is larger than one bite-size, but do not chew yet. Feel it on your tongue: its weight, temperature, size, texture. Explore the sensations of it in your mouth.
When you are ready, intentionally bite into it. Does it go automatically to one side of the mouth? Notice when the taste releases. Slowly, slowly chew, noticing the change in consistency, until you are conscious of the impulse to swallow. Sense the food moving down to your throat and into your oesophagus on its way to your stomach. Sit with the experience, noticing any vestiges remaining in your mouth, on your tongue, any taste, feelings… satisfaction, pleasure, aversion.
Take a moment to congratulate yourself for taking the time to experience Mindful Eating.

Supplementary Table 1.2.
Proposed (nonexhaustive) list of study design features of MBI as recommended by Van Dam et al. (2017) and whether these features are reported in this thesis.

Section/Topic	Number	Item	Study 1	Study 2	Study 3
Teacher information	1	Number/type of retreats attended	N	N	N
	2	Experience in contemplative instruction (general and specific)	Y	Y	Y
	3	Formal contemplative training	Y	Y	Y
	4	Formal clinical qualifications	N	N	N
	5	Blinded to experimental hypotheses	Y	Y	Y
Practice information	6	Setting(s)	Y	Y	Y
	7	Physical (e.g., hospital room, university lecture hall, etc.)	N	N	N
	8	Social (e.g., individual vs. group—if group, cohesion, size)	Y	Y	Y
	9	Overall duration (e.g., 8 weeks, 12 weeks, 3 months, etc.)	Y	Y	Y
	10	Frequency of meetings	N/A	N/A	N/A
	11	Average length of meetings	N/A	N/A	N/A
	12	Types of formal practice (e.g., body scan, breath meditation, walking meditation, etc.)	Y	Y	Y
	13	Approximate total % of each type of practice	N	N	N
	14	Types of informal practice	Y	Y	Y
	15	Logs maintained? Practice reviewed in session? Guided?	N	Y	Y
	16	Types of instructional materials used (e.g., mindfulness-based stress reduction workbook)	N	N	N
General information	17	Instructor adherence assessed	N/A	N/A	N/A
	18	Control group used	Y	Y	Y
	19	Randomization/allocation method	Y	Y	Y
	20	Adverse events monitored	N	Y	Y
Participant information	21	Inclusion/exclusion criteria	Y	Y	Y
	22	Prior meditation experience	N	N	N
Conflicts of interest	23	Formal: funding agency	Y	Y	Y
	24	Informal: Any possible financial benefit from results of study	N	N	N

Notes. N = No, Y = Yes, N/A = Not applicable in this study.

CHAPTER 3: SUPPLEMENTS

Supplements for Chapter 3 include:

S 3.1. Perceptions of app use paragraph: Precise scripts of app conditions

S 3.2. Moderation Table

S 3.3. Moderation Figure

S 3.4. Post hoc analyses

S 3.5. Focus group materials

S 3.6. Manuscript: The peril of self-reported adherence in digital interventions: a brief example.

Supplement 3.1. Perceptions of app use paragraph: Precise scripts of app conditions

Mindfulness app conditions. "Mindfulness is the practice of paying attention in a particular way; on purpose, in the present moment, and non-judgmentally. Mindfulness is both a practice and a state of mind. For example, typically when you practice mindfulness meditation, you're sharpening your focus (usually by paying more attention to your breath) and training your brain to be more mindful long after you've finished meditating. When you're exhibiting mindfulness, you're fully engrossed in whatever's going on around you. By practicing mindfulness people have reported becoming more focused, more creative, happier, healthier, more relaxed, and in control. It can also help you more fully appreciate each precious current moment. However, being mindful isn't as simple as deciding to be mindful, like any skill it becomes easier with practice. In short, mindfulness is about tuning in and being more aware of every experience."

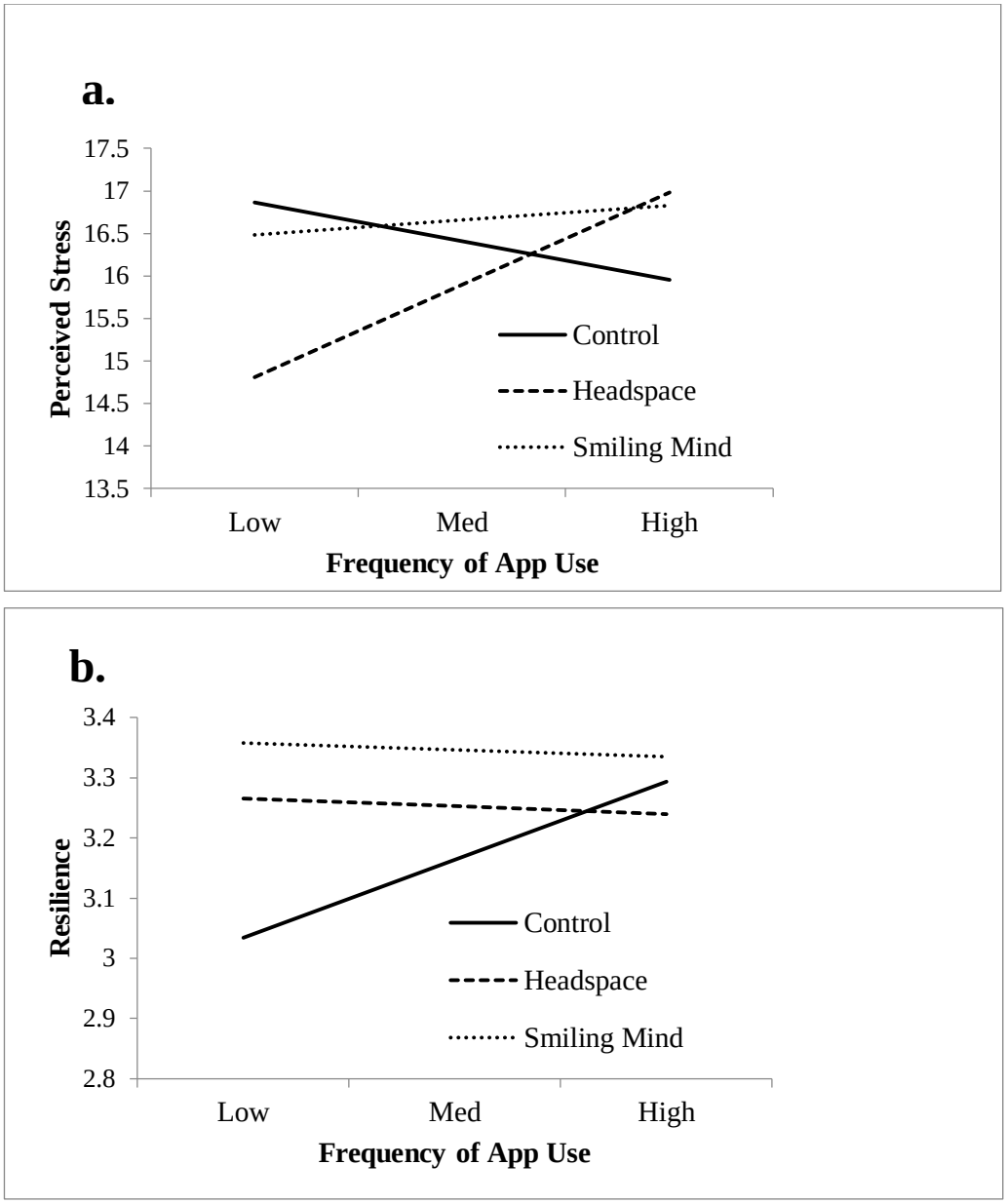
Attention Placebo control app condition. "Organisational Reminiscing (OR) is the practice of paying attention to past behaviours, experiences, and activities in a particular way; on purpose and with awareness of the self. For example, typically when you practice OR, you're sharpening your focus (usually by taking time to sit and deliberately reminisce over past behaviours, experiences, and activities) and training your brain to be more reminiscent long after you've finished engaging in OR. By practicing OR people have reported becoming more focused, more creative, happier, healthier, more relaxed, and in control. However, being reminiscent isn't as simple as deciding to be reminiscent, like any skill it becomes easier with practice. In short, organisational reminiscing is about reminiscing on past behaviours, experiences, and activities to become more aware of every experience."

Supplementary Table 3.2.

Moderator analyses testing how app usage during the 10-day period moderated the effect of experimental condition on changes in mental health outcomes from Time 0 to Time 1. The Time 0 outcome was controlled in all analyses.

	Outcomes						
Predictors	Depressive Symptoms B(SE)	Anxiety B(SE)	Stress B(SE)	Resilience B(SE)	Flourishing B(SE)	College Adjustment B(SE)	Mindfulness B(SE)
Intercept (Control)	16.12 (.75)***	6.36 (.31)***	16.41 (.47)***	3.16 (.05)***	44.39 (.65)***	79.52 (1.20)***	31.23 (.42)***
Outcome covariate at Time 0 (centered)	.77 (.05)***	.72 (.04)***	.83 (.05)***	.76 (.04)***	.91 (.06)***	.79 (.05)***	.87 (.05)***
Dummy 1 (Control vs. Headspace)	-3.67 (1.05)**	-.68 (.43)	-.51 (.67)	.09 (.07)	.39 (.90)	5.60 (1.68)**	1.48 (.58)*
Dummy 2 (Control vs. Smiling Mind)	-3.20 (1.09)**	-.72 (.45)	.25 (.69)	.18 (.08)*	.73 (.94)	4.53 (1.76)*	.26 (.61)
App Usage (centered)	.06 (.42)	-.13 (.18)	-.23 (.27)	.07 (.03)*	-.04 (.36)	.44 (.67)	.15 (.23)
Dummy 1 x App Usage	.35 (.55)	-.07 (.23)	.79 (.35)*	-.10 (.04)*	-.34 (.48)	-.28 (.89)	-.23 (.31)
Dummy 2 x App Usage	-.13 (.57)	-.10 (.24)	.32 (.36)	-.09 (.04)*	.15 (.49)	.49 (.92)	.14 (.32)
Intercept (Headspace)	12.45 (.73)***	5.69 (.30)***	15.90 (.47)***	3.25 (.05)***	44.78 (.63)***	84.94 (1.18)***	32.71 (.41)***
Outcome covariate at Time 0 (centered)	.77 (.05)***	.72 (.04)***	.83 (.05)***	.76 (.04)***	.91 (.06)***	.79 (.05)***	.87 (.05)***
Dummy 2 (Headspace vs Smiling Mind)	.47 (1.08)	-.05 (.45)	.76 (.69)	.09 (.08)	.35 (.93)	-1.07 (1.74)	-1.22 (.60)*
Dummy 3 (Headspace vs Control)	3.67 (1.05)**	-.68 (.43)	.51 (.67)	-.09 (.07)	-.39 (90)	-5.60 (1.68)**	-1.48 (.58)*
App Usage (centered)	.41 (.37)	-.19 (.15)	-.56 (.23)*	-.03 (.03)	-.38 (.31)	.16 (.59)	-.08 (.20)
Dummy 2 x App Usage	-.47 (.53)	-.03 (.22)	-.47 (.34)	.01 (.04)	.50 (.46)	.77 (.86)	.37 (.30)
Dummy 3 x App Usage	-.35 (.55)	.07 (.23)	-.79 (.35)*	.10 (.04)*	.34 (.48)	.28 (.89)	.23 (.31)

Note: * $p < .05$; ** $p < .01$; *** $p < .001$. Dummy Code 1 = 0 (Control), 1 (Headspace), 0 (Smiling Mind). Dummy Code 2 = 0 (Control), 0 (Headspace), 1 (Smiling Mind). Dummy Code 3 = 1 (Control), 0 (Headspace), 0 (Smiling Mind).



Supplementary Figure 3.3. The association between frequency of app use during the 10-day requested use of app and mental health (a: perceived stress, b: resilience) scores for control, Headspace, and Smiling Mind app users at Time 2 controlling for time 0 mental health scores. Frequency of app use was modelled around -1SD, *M*, +1SD, for Low, Med, and High app. *N.B.* Perceived Stress scores can range between 0 – 40 with higher scores indicating greater symptoms of stress. Resilience scores can range between 1 – 5 with higher scores indicating greater resilience.

Supplementary Table 3.4.

Multiple regression analysis of changes in mental health outcomes by experimental condition from Time 0 to Time 1 (left columns), and from Time 0 to Time 2 (right columns). The Time 0 outcome and expectation scores were controlled in Time 0 to Time 1 analyses. The Time 0 outcome and Time 1 perception scores were controlled in Time 0 to Time 2 analyses. Baseline personal growth was controlled in all analyses.

	Outcomes						
Predictors	Depressive Symptoms B(SE)	Anxiety B(SE)	Stress B(SE)	Resilience B(SE)	Flourishing B(SE)	College Adjustment B(SE)	Mindfulness B(SE)
Control (Constant)	15.86*** (.75)	6.27*** (.31)	15.98*** (.47)	3.22*** (.05)	44.40*** (.64)	79.92*** (1.21)	31.37*** (.41)
Outcome at Time 0 (centered)	.74*** (.05)	.73*** (.05)	.76*** (.05)	.74*** (.04)	.90*** (.07)	.78*** (.05)	.86*** (.05)
Personal growth at Time 0 (centered)	-.10 (.07)	-.02 (.03)	-.13** (.04)	.01 (.00)	.02 (.06)	.15 (.10)	.04 (.04)
Expectation/Perception (centered)	-1.36* (.68)	-.23 (.29)	-.27 (.43)	-.02 (.05)	1.97** (.57)	.30 (1.11)	.58 (.38)
Control vs. Headspace	-3.70*** (1.02)	-.61 (.43)	-.57 (65)	.07 (.07)	.40 (.87)	5.43** (1.66)	1.43* (.57)
Control vs. Smiling Mind	-2.32 (1.24)	-.44 (.52)	1.53 (.78)	.08 (.09)	.67 (1.07)	2.70 (1.99)	-.19 (.68)
Control (Constant)	15.97*** (1.05)	6.76*** (.45)	15.64*** (.66)	3.26*** (.07)	44.49*** (.87)	81.98*** (1.58)	31.40*** (.56)
Outcome at Time 0 (centered)	.78*** (.07)	.63*** (.07)	.75*** (.07)	.71*** (.05)	.77*** (.09)	.71*** (.06)	.75*** (.06)
Personal growth at Time 0 (centered)	-.15 (.09)	-.04 (.04)	-.13* (.06)	.01* (.01)	.17* (.08)	.30* (.13)	.09 (.05)
Expectation/Perception (centered)	-.98 (.85)	-.12 (.37)	-.75 (.55)	.06 (.06)	.79 (.69)	1.52 (1.30)	.57 (.45)
Control vs. Headspace	-3.13* (1.47)	-1.04 (.63)	-.41 (.94)	.20* (.10)	.51 (1.20)	3.45 (2.21)	1.02 (.78)
Control vs. Smiling Mind)	-1.57 (1.71)	-.78 (.73)	1.51 (1.07)	-.07 (.11)	.13 (1.42)	-.79 (2.55)	-.35 (.90)

Note: * $p < .05$; ** $p < .01$; *** $p < .001$. Dummy Code 1 = 0 (Control), 1 (Headspace), 0 (Smiling Mind). Dummy Code 2 = 0 (Control), 0 (Headspace), 1 (Smiling Mind). Dummy Code 3 = 1 (Control), 0 (Headspace), 0 (Smiling Mind).

Supplement 3.5. Focus Group Materials

A moderator's guide was developed in accordance with Krueger's guidelines (cite) to provide the moderator with an overview of the purpose of the focus group, a projected timeline, probing and facilitation ideas, and an outline of questions for discussion. the outline consisted of a checklist of major question lines that were to be discussed, with a series of secondary probing questions to facilitate continued discussion (presented below in Table X) to help establish a broader understanding of user experiences of the mobile apps. This checklist was used to steer the discussion towards a major topic if the participants failed to address the topic on their own accord. The focus group questions were developed to tap into facets of the 3 primary research questions (with an additional question for study participation feedback) and were loosely based on questions used in a semi-structured interview of mobile mindfulness users by Laurie (2014). These questions were reviewed by a group of postgraduate health psychology research students who had been involved with piloting the RCT. I collaboratively discussed and revised these questions with the aim of gaining a broad understanding of the user experiences of mobile mindfulness applications.

Table 1
Focus group primary and secondary question lines and associated probes.

Construct	Question line	Question
Effectiveness	Primary	How effective do you think the mindfulness meditation programme is and do you think it works as an app?
	Secondary	Do you think using this app has had an effect on your life? In what ways and how?
	Secondary	Did the app "work" for you? Why? Why not? (N.B. this is intentionally ambiguous)
	Secondary	What motivated you to use the app?
	Secondary	Have you noticed any changes that have occurred in your life as a result of using this app? Can you think of changes you have made in your life that you can relate to using the app?
	Secondary	How have emotions affected how you have used or experienced the app?
	Secondary	Did you use the app after the initial 10-day trial? Why? Why not?
Barriers	Primary	What were the barriers or things that stopped you from using the app?
	Secondary	Were there any breaks in your use of the app and what caused those breaks? What made you start again?
	Secondary	Were there ever times when you aimed to use the app but didn't manage to? What stopped you from using the app on these occasions?
	Secondary	How did your intention to use the app change as you continued?
	Secondary	Were there people, circumstances, events or objects that affected the way you used the app? Tell me about these.
	Secondary	Was there ever a time when you thought the app was a waste of time or too much hassle to really be worth it? Tell me about this.

User impressions	Primary	What were your initial impressions when you first opened and used the app?
	Secondary	What did you like or dislike about the app and using the app?
	Secondary	Talk me through how you have used the app during the study. Probes: When and where did you use it? Did it change over the study? How often? How many days? How did you fit the app into your life? When were you most likely to use the app?
	Secondary	Was there ever a time when you thought 'this app is great. I'm glad I'm using it'? Tell me about this.
	Secondary	How did the built-in reminders influence your use of the app?
Participation	Primary	Did the study run well? In what ways?
	Secondary	Was there anything you wish we did differently?
	Secondary	Did the daily survey help you to remember to use the app and in what ways?
	Secondary	Did the daily survey hinder you during the study and in what ways?
	Secondary	Do you think this study dissuaded you from using the app in the future? If someone were to offer you the use of the app would you take them up on their offer?

Supplement 3.6. Manuscript entitled: THE PERIL OF SELF-REPORTED ADHERENCE IN DIGITAL INTERVENTIONS: A BRIEF EXAMPLE

Reference

Flett, J. A. M., Fletcher, B. D., Riordan, B. C., Patterson, T., Hayne, H., & Conner, T. S. (In Press). The peril of self-reported adherence in digital interventions: a brief example. *Internet Interventions*.

Abstract

Adherence is an important predictor of intervention outcomes, but not all measures of adherence are created equally. Here, we analysed whether there was a discrepancy between self-report adherence and objective adherence in a digital mindfulness meditation randomised, controlled trial. A sample of 174 young adult undergraduate university students trialled either an app-based or email-based mindfulness meditation program (or an app-based attention control). Participants' adherence (number of sessions completed) and mental health was self-reported. Objective adherence data were provided by the owners of the digital mindfulness programs. We found evidence of inflated self-reported adherence to the app-based intervention and argue that the inflation was not explained by social desirability biases because participants were aware we would have access to object data and no remuneration was tied to adherence. We also comment on the different conclusions we would have drawn about the effectiveness of the digital interventions on mental health, had we used the self-reported adherence data rather than the objective adherence data. We use this example to suggest that it may be perilous to rely on self-reported measures of adherence when assessing the effectiveness of digital interventions.

Keywords

Digital interventions; applications; mobile phones; adherence

Abbreviations

RCT: Randomized, controlled trial; M: Mean, SD: Standard deviation

1. Introduction

Between 2009 and 2015, yearly publications on e-mental health interventions trebled (Firth, Torous, & Yung, 2016), but meta-analytic reviews reveal that self-guided digital interventions often have only modest effects on mental health (Andersson & Cuijpers, 2009; Cuijpers et al., 2011; Spijkerman, Pots, & Bohlmeijer, 2016). One explanation for these modest effects might be that adherence to digital interventions is low (Cuijpers et al., 2011; Eysenbach, 2005). Adherence refers to

whether individuals access the content and use it in the manner it was designed to be optimally effective (Christensen, Griffiths, & Farrer, 2009; Donkin et al., 2011).

To be optimally effective, regular practice is considered a key component of mindfulness-based interventions (Segal, Williams, & Teasdale, 2013) and adherence to practice guidelines is correlated with intervention outcomes (meta-analysis: k = 28, r = .264, p <.001; Parsons, Crane, Parson, Fjorback, & Kyuken, 2017). Likewise, adherence in self-guided iCBT is associated with lower depressive symptoms and stronger responsiveness to treatment (Karyotaki et al., 2017). Outside of digital interventions, adherence is a strong predictor of intervention outcomes, particularly when the health issue is less serious, chronic, non-medicated, in a pediatric population, or where outcomes are not disease specific (DiMatteo, Giordani, Lepper, & Croghan, 2002). Counterintuitively, self-reported adherence is also a strong predictor of intervention outcomes (DiMatteo et al., 2002). But, few digital interventions report adherence rates, and even fewer report how adherence relates to intervention outcomes (Brown et al., 2016; Donkin et al., 2011).

To date, the majority of research on adherence in digital interventions has focused on operationalizing adherence and identifying predictors of adherence (see: Christensen et al., 2009) but the complexity of adherence is often neglected (see: Sieverink, Kelders, & van Gemert-Pijnen, 2017 for a systematic review). Adherence has been operationalized in a number of ways (e.g., for practical reasons metrics such as sessions completed, days used, logins, or a combination of these are often used; Donkin et al., 2011; Donkin et al., 2013; Sieverink et al., 2017) but the measures often fail to capture the quality of the engagement with the intervention (e.g., were skills acquired), nor do they distinguish between observed adherence (how much the individual experienced the content of the intervention) and prescribed adherence (how much the individual experienced the intervention as recommended or intended; Kelders, Kok, Ossebaard, & Van Gemert-Pijnen, 2012; Sieverink et al., 2017). Further, few digital interventions report or justify the level of adherence required to make the intervention work and instead rely on a 'more-is-more' approach (Sieverink et al., 2017) that presupposes that the dose-response relationship is linear. But, a linear dose-response relationship between adherence and outcomes is not always the case (e.g., Donkin et al., 2013; Blanck et al., 2018). Researchers have identified a host of additional factors that influence adherence including persuasive intervention design (Kelders et al., 2012), amount of support provided (Andersson & Cuijpers, 2009; Christensen et al., 2009), and participant characteristics (Christensen et al., 2009).

Another important but overlooked issue is the accuracy of self-reported adherence in digital interventions. Although self-reported adherence data are easily collected, they may be subject to biases that affect all self-report data (e.g., recall bias and response bias; Kimberlin & Winterstein,

2008; Schwarz, 1999), which may lead to inaccurate conclusions about the effectiveness of the intervention. Researchers can mitigate recall and response biases in self-report data by using research designs like experience sampling or daily diaries to reduce recall time (Schwarz, 2012) or by nonjudgmentally acknowledging normality of non-adherence[45] and anonymizing online reports of sensitive topics to reduce socially desirable responding (Gnambs & Kaspar, 2015). A more direct approach would be to use objective measures of adherence. In contrast to some other interventions, objective measures of adherence are readily available in digital interventions in the form of number of logins, sessions completed, or minutes completed (Donkin et al., 2011) and can be used to measure adherence differences across intervention platforms (Morrison et al., 2018). In the current short report, we demonstrate the peril of relying on self-reported adherence by comparing the discrepancies between self-reported and objectively-gathered adherence data in web-based and app-based digital mindfulness meditation interventions.

Design. This study was a protocol replication of an earlier study (Flett et al., 2018) with a few minor adaptations. The study was a 40-day randomised, controlled trial (RCT) comparing the use of one of two mindfulness meditation programs (or an attention control) on changes in mental health (University of Otago ethics committee #D15/063). A convenience sample of 174 undergraduate university students (*M* = 19.76 years, *SD* = 2.56 years, 79.9% female, 71.8% New Zealand European/Pākehā)[46] were randomly assigned to use either an app-based mindfulness program (Headspace, *n* = 65), an email-based mindfulness program (10 Minute Mind, *n* = 51), or an app-based attention control program (Evernote, *n* = 58). We recommended that participants use their program for 10 minutes per day. This period was equivalent to one session of the intervention and was consistent with previous digital mindfulness research (e.g., Flett et al., 2018; Howells, Ivtzan, & Eiroa-Orosa, 2016). We measured self-reported and objective adherence over two time periods: 1)

[45] This is a recommended practice in pharmaceutical treatments (see: Stirratt et al., 2015) but could be applied in digital interventions i.e., telling participants "it's okay if you miss a planned session, just start again when you can".

[46] Given these analyses concern the accuracy of self-reported data, we followed a per protocol procedure where we analyzed cases where participants provided data. The original sample was 185 young adult undergraduate university students (*M* = 19.75 years, *SD* = 2.50 years, 80.5% female, 70.8% New Zealand European/Pākehā). Consistent with previous mindfulness-based self-help interventions (Cavanagh, Strauss, Forder, & Jones, 2014), attrition rates were low (3.2%, *n* = 6) at Day 10, but were moderate (27.0%, *n* = 50) at Day 40. An ID error meant we were unable to attain objective adherence data for 5 email-based participants; these participants were excluded from the adherence-based analyses. Total *n* at Day 10 = 174; Total *n* at Day 40 = 131. Including all participants randomised at baseline (*n* = 185), no demographic variables predicted attrition (*r*s -.013 – .093, *p*s =.210 – .861). Completion of Day 10 and Day 40 surveys was not correlated with any baseline mental health characteristics (*r*s -.001 – .099, *p*s .179 -.986). There was a negative correlation between completing Day 10 survey and extraversion (*r* = -.196, *p* =.008) and a positive correlation between completing the Day 40 survey and conscientiousness (*r* = .198, *p* = .018), although we were not adequately powered to detect correlations this small (Gignac & Szodorai, 2016), so caution is warranted.

Prescribed adherence: a 10-day period where adherence was requested each day and 2) Discretionary adherence: a 30-day period where adherence was at the discretion of the individual (mimicking more realistic or natural uptake). Both mindfulness interventions (Headspace and 10 Minute Mind) involved similar active therapeutic components (e.g., they introduced mindfulness through a series of brief formal mindfulness practices such as mindful breathing [using the breath as an attentional object of intense focus] and body scanning [systematically focusing on certain parts of the body]). Access to the interventions followed a hybrid structure whereby the interventions involved fixed core content with additional optional components (Sieverink et al., 2017); app-users had to complete the first 10 sessions consecutively in order to 'unlock' other intervention content, whereas email-users were emailed new sessions each day but had access to brief mindfulness "top up" sessions (optional 3-minute meditations). For email-based participants, all intervention sessions were 10 minutes long, whereas, for app-based participants the first 10-sessions were 10 minutes long, but longer sessions (up to 45 minutes long) were available during the 30-day Discretionary adherence period.

Procedure and measures. All participants reported their mental health (depressive symptoms, anxiety, stress, flourishing, resilience, mindfulness, and adjustment to college: measures described in Flett et al., 2018) on Day 0 in the research lab (baseline; also, demographic and personality characteristics using the NEO-FFI 60, Costa & McCrae, 1992), and online on approximately Day 10 and Day 40. Self-reported and objective adherence were operationalised as the number of intervention sessions completed; this was a pragmatic operationalisation based on the available objective use data. Self-reported adherence was measured daily during the first 10 days as well as retrospectively on Day 10 and Day 40 with a single item survey question ("how many times did you access the app in the preceding study period"). Objective adherence data were also provided by the owners of the mindfulness programs, which gave us the number of times each user completed a session using their mindfulness program. To reduce the likelihood of socially desirable responding, adherence was not tied to any form of remuneration and participants were aware that we would be provided with their objective adherence data. Participants used their participation to obtain a small portion of course credit tied to survey completion (not app use). Except where specified, we only present results for the mindfulness conditions because we did not have access to objective adherence data for the app-based Attention Control program.

2. Results

Discrepancies between self-reported and objective adherence were calculated by subtracting objective adherence from self-reported adherence (self-report – objective = discrepancy) during the 10 days of prescribed adherence (discrepancies were calculated for both retrospective and daily self-reported adherence) and for the 30 days of discretionary adherence (retrospective only). Positive

values indicated over-reporting of adherence and negative values indicated under-reporting of adherence. Adherence discrepancies were assessed using two-way mixed ANOVA (self-report vs objective; app-based user vs email-based user) with Bonferroni adjustment. In Supplementary Tables 2-9 we present descriptive statistics and tests comparing all major outcomes over time within (S Table 2) and between conditions (S Table 3), moderation by adherence (S Table 4-7), and correlations between adherence measures and demographic, personality, and outcome measures by condition (S Table 8-9).

Discrepancies between self-reported and objective adherence

As shown in Table 1, the discrepancy between self-reported and objective adherence differed by digital platform (app vs. email), particularly for the longer time period. Only app-users showed significant discrepancies between self-report and objective measures of adherence. App users self-reported doing 1.54 more sessions than they objectively did during the 10-day prescribed use period and 9.13 more sessions than they objectively did during the discretionary 30-day time period (D11-40). By contrast, for email-based intervention users, the discrepancy was negligible during both the 10-day prescribed adherence period (over-reported by about .3 sessions for both retrospective and daily self-report, not significant) and the 30-day discretionary adherence period (over-reported by 3.00 sessions, not significant). In fact, app users over-reported their adherence by over three times as much as email users when adherence was discretionary across 30 days (e.g., App: M = 9.13, SD = 7.84 vs. Email: M = 2.58, SD = 11.40) and almost 35 times as much overall (e.g., App: M = 8.62, SD = 9.24 vs. Email: M = -.25 SD = 13.91). Furthermore, during the 10-day prescribed adherence period, there were no differences between daily and retrospective self-report of adherence for the sample overall (t(171)= .13, p =.899) or within conditions (all ps >.581; Supplementary Table 1),[47] suggesting that daily reports of adherence during the 10-day period were no more accurate than retrospectively recalling their adherence at the end of the 10 days.

Effect of intervention and adherence on outcomes

We found no consistent nor convincing evidence that mental health changed over time within conditions (S Table 2), nor that intervention condition (app-based or email-based) predicted change in mental health at Day 10 or Day 40 (controlling for Day 0 outcome; all condition model ps >.05; S Table 3). Likewise, we found no consistent nor convincing evidence that adherence (self-reported or objective) predicted change in mental health at Day 10 or Day 40 (controlling for Day 0 outcome; all adherence model ps >.05 following adjustment for multiple comparisons; S Tables 4-7). Finally, there

[47] All Supplements for this manuscript are available at the online archive of this manuscript: https://doi.org/10.1016/j.invent.2019.100267

were no consistent predictors of self-reported or objective adherence that help explain the app-based or email-based differences in over-reported adherence (S Tables 8-9).

Table 1

Means (M) and standard deviations (SD) of self-reported and objective adherence when adherence was prescribed (Days 0-10, daily and retrospective), discretionary (Days 11-40), and overall (Days 0-40) for all conditions (self-report descriptive statistics only for controls). F tests indicate the results of the mixed ANOVA.

Adherence		Self-report		Objective		Over-report [a]			Self-report vs Objective			App-based vs email-based over-reporting [b]		
App- and Email-combined	*n*	*M*	*SD*	*M*	*SD*	%	*M*	*SD*	*F*	*df*	*p*	*F*	*df*	*p*
Prescribed D0-10 Retro	116	7.87	2.14	6.87	3.53	14.6	1.00	3.44	8.49	1,114	.004	3.71	1,114	.057
Prescribed D0-10 Daily	116	7.84	2.50	6.87	3.53	14.1	.97	3.93	5.99	1,114	.016	2.70	1,114	.103
Discretionary D11-40	89	12.42	8.29	5.83	8.79	49.8	6.58	9.83	36.02	1, 87	<.001	9.21	1, 87	.003
Overall D0-40 Retro	116	17.48	9.55	12.73	10.87	37.3	4.75	11.81	16.78	1,114	<.001	18.71	1,114	<.001
Overall D0-40 Daily [c]	116	17.45	9.71	12.73	10.87	37.1	4.72	12.30	15.04	1,114	<.001	16.93	1,114	<.001
App-user														
Prescribed D0-10 Retro	65	8.45	2.08	6.91	4.29	22.3	1.54	3.69	13.32	1,114	<.001			
Prescribed D0-10 Daily	65	8.40	2.08	6.91	4.29	21.6	1.49	4.18	9.51	1,114	.003			
Discretionary D11-40	52	12.23	8.31	3.10	6.77	294.5	9.13	7.84	49.10	1, 87	<.001			
Overall D0-40 Retro	65	18.23	9.78	9.57	8.78	90.5	8.66	8.93	40.33	1,114	<.001			
Overall D0-40 Daily [c]	65	18.18	9.76	9.57	8.78	90.0	8.62	9.24	36.33	1,114	<.001			
Email-user														
Prescribed D0-10 Retro	51	7.14	2.61	6.82	2.26	4.7	.31	2.98	.43	1,114	.551			
Prescribed D0-10 Daily	51	7.12	2.81	6.82	2.26	4.4	.29	3.51	.29	1,114	.591			
Discretionary D11-40	37	12.68	8.37	9.68	9.89	31.0	3.00	11.25	3.77	1, 87	.050			
Overall D0-40 Retro	51	16.53	9.26	16.76	11.98	-1.4	-.24	13.17	.02	1,114	.879			
Overall D0-40 Daily [c]	51	16.51	9.66	16.76	11.98	-1.5	-.25	13.91	.02	1,114	.875			
Attention Control														
Prescribed D0-10 Retro	58	8.62	2.15											
Prescribed D0-10 Daily	56	8.43	2.15											
Discretionary D11-40	42	11.33	10.56											
Overall D0-40 Retro	58	17.02	11.29											
Overall D0-40 Daily [c]	58	16.83	11.15											

[a] Over-reporting = Self-report – Objective, % = ((Self-report/Objective)*100) - 100; Positive values indicate number of sessions where adherence was over-reported in a time period.

[b] Interaction from Two-Way Mixed ANOVA showing the difference between self-reported vs objective adherence varied by platform.

[c] Overall using Prescribed D0-10 Daily and Discretionary D11-40.

Discussion

Self-reported adherence –whether reported daily, or retrospectively– was not an adequate representation of app-based intervention adherence. When adherence was at the discretion of the user and occurred over a month-long period, which is more representative of realistic mindfulness meditation platform usage, self-reported app adherence was even less reliable. In fact, the discrepancy between self-reported and adherence to the app during that longer period was staggering – 12 sessions self-reported versus only 3 sessions actually logged. This discrepancy occurred even though participants were aware that we would receive access to their objective adherence data and that remuneration (i.e., course credit) was not contingent on adherence. So, the over-reporting does not appear to be the result of social desirability response biases. Over-reporting app use was also not ameliorated by self-reporting app use each day, which suggests that even daily reporting of adherence is problematic.

Interestingly, adherence was more accurate for the email-based intervention than the app-based intervention. This could be due to the email intervention being more unusual and requiring more effort to enact, which would enhance memory for the session. The email-based mindfulness program was delivered to students' university email address on a platform that is not particularly mobile-friendly. As a result, participants would have likely accessed their intervention using a PC or laptop (indeed, several participants reported that they were unable to easily access the email-based intervention using their mobile phones). By contrast, the app intervention integrated seamlessly into participants' lives, requiring less effort to enact, which could reduce memory for the session. Given that young adults spend on average between 2-4 hours per day on their mobile phones (Montag et al., 2015, sample primarily from Germany; Liao, Doad, Gross, & Hayne, In Review, sample from New Zealand) and more than two-thirds of global internet use in 2017 was completed on mobile devices rather than laptops (Enge, 2018), it may be that the app-based mindfulness intervention was less salient (and more subject to memory biases) than the relatively more unusual email-based mindfulness intervention. The meditation instructor was a New Zealander, so this may have been more salient to our New Zealand-based participants. Whether other plausible mechanisms explain this modality-based discrepancy in over-reporting requires further research; however, it might be a less relevant question in the future as digital interventions continue to increase in technological sophistication.

The objective adherence data may explain the null effects for this particular intervention. We found no evidence that the digital mindfulness interventions improved mental health over time (Day 10 or Day 40: see Supplementary Table 2 and Table 3 for detail). In the absence of adherence data, we naturally would have concluded that the interventions were not effective. However, objective

adherence showed that intervention use was much too low to be effective. Given that face-to-face mindfulness programs typically recommend 45 minutes of home practice, six days per week (Segal et al., 2013), it is unlikely that three sessions of the mindfulness meditation app over the course of 30 days would qualify as a sufficient dose of a psychotherapeutic intervention to produce any lasting or meaningful benefits. This interpretation fits with previous literature that suggests increased adherence is associated with intervention outcomes (Karyotaki et al., 2017; Parsons et al., 2017). However, it could also be that any effects were present but short-lived (occurring only on days of use) (Schumer, Lindsay, & Cresswell, 2018). This is also the case in other brief or 'microinterventions' (Elefant, Contreras, Muñoz, Bunge, & Leykin, 2017).

In conclusion, our results suggest that self-reported adherence to app-based intervention trials is suspect, particularly over longer time periods. We present this data as a brief cautionary tale about the peril of relying on self-reported adherence when assessing the effectiveness of digital interventions, and app-based interventions in particular. If self-reports of adherence are inflated, researchers and clinicians may both over-estimate the acceptability of a tool (i.e., thinking usership is higher) and under-estimate the effectiveness of a tool (although, this only holds provided there is a positive relationship between adherence and outcomes). Objective adherence data is recommended to determine whether people access the content and use their digital interventions in the intended manner of use.

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Declaration of Interest

The authors declare that there are no conflicts of interest with respect to the authorship or the publication of this article. Headspace and the 10 Minute Mind provided free access to their digital mindfulness meditation programs and provided adherence data (with participants permission) but they were not involved in research design, analyses, and have no part in publication of this research. The Memorandum of Understanding between Headspace and the research institution is available on request.

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This article does not contain any studies with animals performed by any of the authors.

Data statement

Deidentified data are available on request.

CHAPTER 4: SUPPLEMENTS

Supplements for Chapter 4 include:

S 4.1. Randomisation detail in line with CONSORT checklist

S 4.2. Participant demographics

S 4.3. Examples of automated emails to participants

S 4.4. Trial safety protocol

S 4.5. Memorandum of Understanding between Headspace and the University of Otago

Supplement 4.1. Randomisation detail required by CONSORT checklist

Randomisation was built into our study portal by Hadyn Youens, Department of Psychology programmer involved in this study.

Randomisation:			Response
Sequence generation	8a	Method used to generate the random allocation sequence	The participant was placed in one of three groups. On being placed in a group, a count was done on how many people of the participant's specified gender were in each of the groups. The participant was then placed in the group with the least number of current participants with the same gender, or if they had the same number: Group one, then Group, two, then Group three.
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	There was an order to which group a participant was put in, for the purposes of keeping an even number of each gender in each group, further to this the randomness was achieved through the chronological order of participants being registered into the study.
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	After a participant provided consent and completed the baseline survey (where they reported demographic details such as gender), the computer would automatically assign them to a group. Only those with access to the source code of the software had the ability to see how groups were allocated. That is, only Hadyn Youens had access to this information
Implementation	10	Who generated the random allocation sequence	Completely generated by computer using code written by Hadyn Youens.

Supplementary Table 4.2.

Demographic characteristics by condition using complete case (per-protocol) data

	Overall		HS Pre-counselling		HS Counselling-onset		HS Post-counselling		*Chi Square* (One Way ANOVA)		
	n	%	*n*	%	*n*	%	*n*	%	X^2 *(F)*	*df*	*p*
n	86		33	38.4	26	30.2	27	31.4			
Age (*M, SD*)	21.15	3.87	21.45	4.19	21.13	4.26	20.76	2.98	.19	2, 71	.829
Gender[a]											
Women/Female	72	83.7	27	81.8	22	84.6	23	85.2			
Men/Male	12	14.0	4	12.1	4	15.4	4	14.8			
Other/Unsure	2	2.3	2	6.0	0	0.0	0	0.0			
Ethnicity[b]											
NZ European/ Pākehā	67	77.9	28	84.8	20	76.9	19	70.4	1.25	2	.535
Māori	8	9.3	4	12.1	1	3.8	3	11.1	1.27	2	.531
Pasifika	3	3.5	1	3.0	1	3.8	1	3.7	.05	2	.977
Chinese	5	5.8	0	0.0	3	11.5	2	7.4	3.86	2	.145
Indian	3	3.5	2	6.1	1	3.8	0	0.0	1.57	2	.456
Other	9	10.5	2	6.1	3	11.5	4	14.8	1.38	2	.501
Accommodation									15.22	10	.124
Residential College	15	17.4	5	15.2	4	15.4	6	22.2			
Flatting	49	57.0	22	66.7	16	61.5	11	40.7			
Parental home	4	4.7	0	0.0	2	7.7	2	7.4			
In a home you own	1	1.2	1	3.0	0	0.0	0	0.0			
Boarding	1	1.2	0	0.0	0	0.0	1	3.7			
In a studio room	3	3.5	0	0.0	0	0.0	3	11.1			
Year at university									5.51	10	.855
1st year	18	20.9	6	18.2	8	30.8	4	14.8			
2nd year	19	22.1	7	21.2	6	23.1	6	22.2			
3rd year	17	19.8	6	18.2	4	15.4	7	25.9			
4th or 5th year	10	11.6	5	15.2	2	7.7	3	11.1			
Postgraduate: Masters, PgDip, etc	5	5.8	2	6.1	2	7.7	1	3.7			
Postgraduate: PhD	4	4.7	2	6.1	0	0.0	2	7.4			

Note. *a* Gender was a free text question. I recategorised the free text on the basis of the above free text entries i.e., one person said other; one person said unsure
b Ethnicity data total greater than 100% because participants may identify with multiple ethnicities.

Supplementary 4.3. Automated emails to participants

INITIAL EMAIL – INFO, CONSENT

Subject line: Mobile Mindfulness Meditation – Research study

Hello,

Earlier this week you indicated you were interested in hearing more about an online trial of a mobile mindfulness meditation app taking place at University of Otago's Student Health Services. Firstly, thank you for showing an interest in this project! Secondly, before you can take part in this project, we must ask you to read the online information sheet and complete the online consent form.

Enclosed in this email is an information sheet for all potential participants. We recognise that this information sheet is long but please read it carefully and take time to consider (and, if you wish, talk with relatives or friends) before deciding whether or not to participate. If you decide to participate, we thank you. If you decide not to take part there will be no disadvantage to you and we thank you for considering our request.

Should you decide to participate, there is a link here **(insert link)** and at the bottom of the email which will direct you to the online consent form and the first (and by far the longest) survey for this project. This survey should take you approx. 20 minutes.

All the best,

Dr. Tess Patterson (Principal Investigator; tess.patterson@otago.ac.nz) and the Mobile Mindfulness Team

CONDITION EMAIL

Subject line: Mobile Mindfulness Meditation – Research study – Study details for future reference

Hello,

Thank you for signing up to take part in this study! We appreciate your help.

Recall that you read the information sheet earlier? In order to ensure you know what is going on at any stage during this study we thought we would send you a copy of the information sheet.

In addition the image below depicts a timeline for your participation in this study.

INSERT IMAGE 1, 2, or 3 – depending on group

Attach pdf of information sheet.

All the best,

Dr. Tess Patterson (Principal Investigator; tess.patterson@otago.ac.nz) and the Mobile Mindfulness Team

START OF TREATMENT EMAIL

Subject line: Mobile Mindfulness Meditation – Research study

Kia ora,

You should have recently begun some form of treatment with your clinician through Student Health Services' – Counselling Service. This is one of set the survey points for this study.

Here is the link to your next survey. Even if you are no longer interested in the app-based portion of this study, we would really appreciate it if you could complete this survey (approx. 15 minutes, a.k.a. a scientifically perfect amount of time to take a study break! http://time.com/3518053/perfect-break/). By completing this survey you are helping us to better understand both mental health and mobile health interventions.

START OF TREATMENT SURVEY LINK

All the best,

Dr. Tess Patterson (Principal Investigator; tess.patterson@otago.ac.nz) and the Mobile Mindfulness Team

END OF TREATMENT SURVEY

Subject line: Mobile Mindfulness Meditation – Research study

Hello,

You should have recently completed some form of treatment with your clinician through Student Health Services' – Counselling Service. This is one of the final survey points for this study.

Here is the link to your survey. Even if you are no longer interested in the app-based portion of this study, we would really appreciate it if you could complete this survey (approx. 15 minutes, a.k.a. a scientifically perfect amount of time to take a study break! http://time.com/3518053/perfect-break/). By completing this survey you are helping us to better understand both mental health and mobile health interventions.

END OF TREATMENT SURVEY LINK

All the best,

Dr. Tess Patterson (Principal Investigator; tess.patterson@otago.ac.nz) and the Mobile Mindfulness Team

END OF STUDY EMAIL

Subject line: Mobile Mindfulness Meditation – Research study

Hello,

Thank you kindly for taking part in this trial of Headspace, a mobile mindfulness meditation app, during your treatment at Student Health Services – Counselling Service. Your participation and input is greatly appreciated. With your help (and the help of a number of others) we are hoping to see whether Headspace is a useful tool for students who are attending the Student Health Services – Counselling Service.

You may have received access to Headspace at the outset of attending, when you began or when you finished treatment at Student Health Services – Counselling Service. We expect that there are benefits to receiving access to Headspace at each of these time points, which is why we are trialling it, we want to know when the best time to receive access is.

Later in the year we will run an online Q + A session where you can anonymously sign in and ask the researchers questions about this study. In this format we will have additional information about the study. In addition we may ask you for some feedback about the study and your experiences with the app and mindfulness. Any information you provide in this setting may be used as a 'focus group' to help inform future iterations of the study but your details will remain anonymous.

At the end of the year we will have one final survey taking approximately 3 minutes. This is really just a check-in to see how you are and to see whether you are still practicing mindfulness.

Once again, thanks for taking part in our study, without your participation it would not be possible.

Kind regards,

Dr. Tess Patterson (Principal Investigator; tess.patterson@otago.ac.nz) and the Mobile Mindfulness Team

DOWNLOAD HEADSPACE EMAIL

Subject line: Mobile Mindfulness Meditation – Research study – DOWNLOAD HEADSPACE

Hello,

Thank you dearly for taking part in this study! Your next survey will be in 2 weeks' time.

We would now like to ask you to download Headspace, a popular mobile mindfulness meditation application or app. Headspace typically retails at $12.95USD per month but we would like to provide you with full access to the app for the next 30 days using the following voucher code.

To redeem your voucher code you must download Headspace onto your mobile phone and login on to the online portal to redeem the voucher (this typically is a much smoother process if performed on a computer rather than your handheld device).

STEP 1. Download app from your app store on your mobile phone

STEP 2. Access online headspace here (on computer)

STEP 3. Copy and post this code – INSERT CODE – into online portal to redeem your voucher.

STEP 4. Meditate!

Try to **use Headspace at least once a day**, if you miss a day or two, don't worry just get back on board when you can. You can use the app at ANY time of the day, in ANY place you like, just try to use it at least once a day.

Each session takes 10-20 minutes. The Headspace app includes hundreds of hours of original content that is organized into five categories: Foundation, health, relationships, performance, and Headspace pro (see below for more details).

The app is structured so that you must complete at least Foundation Level 1 before accessing other content in the app. Although Foundation 2 and 3 are not compulsory, we recommend they be completed as they are not only an introduction to mindfulness meditation but also an opportunity to get used to Headspace's style of teaching. The other packs in the series library

build on what is taught in these sessions and assume that you have progressed through Foundation Series.

Foundation Series
• Level 1 (10 sessions – 10 minute each)
• Level 2 (10 sessions – 10 or 15 minutes each)
• Level 3 (10 sessions – 10, 15 or 20 minutes each)
Relationships
• Relationships (30 sessions)
• Change (10 sessions)
• Appreciation (10 sessions)
• Acceptance (10 sessions)
Performance
• Creativity (30 sessions)
• Focus (30 sessions)
• Happiness (10 sessions)
• Balance (10 sessions)
Health
• Depression (30 sessions)
• Self-Esteem (30 sessions)
• Stress (30 sessions)
• Anxiety (30 sessions)
• Sleep (30 sessions)
• Pregnancy (30 sessions)
Headspace Pro
• Level 1 (10 sessions)
• Level 2 (10 sessions)
• Level 3 (10 sessions)
• Level 4 (10 sessions)
•Level5(10sessions)

Please note, as indicated in the information sheet and consent form – Headspace will provide our research team with your user data, e.g., what sessions you completed and when you completed them. This will help us more stringently determine the effect mindfulness practice is having on you at both an individual and group level.

If you have any questions about the app, please check out the FAQ's here https://www.headspace.com/faqs if you have any technical issues that aren't resolved using the FAQs, please contact headspace here https://www.headspace.com/contact-us We hope you enjoy using Headspace, however, we would like to remind you that if mobile mindfulness meditation is not right for you in any way or makes you feel increasingly distressed, please cease practice. You are welcome to resume practice at a later stage if you wish to do so. You are also welcome to talk to your clinician about your mindfulness practice.

Please note: If you do cease practice, it is extremely important for you to continue to complete our surveys – we have tried to keep them as brief as possible – with your assistance we will have a better understanding of mental health, the app, and both the positives and negatives of mobile health interventions.

Finally, if you experience distressing feelings or thoughts related to mindfulness app use and these distressing feelings or thoughts are ongoing or are severe enough that you feel concerned about what you experienced, please cease mindfulness meditation and contact Dr. Kim Ma'ia'i or Dr. Jubilee Rajiah. To contact Dr. Ma'ia'i or Dr. Rajiah, please call Student Health Services reception at 03 479 8212 or 0800 479 821 and ask to speak with either Dr. Ma'ia'i or Dr. Rajiah. Dr. Ma'ia'i and Dr. Rajiah are experienced clinicians who will conduct an over the phone clinical assessment in order to determine the appropriate response to your experience. If you are experiencing acute mental health issues or are in need of immediate psychiatric care we would request that you contact Emergency Psychiatric Services and tell them about your experiences. Emergency Psychiatric Service is a mobile 24-hour, 7-day a week service providing emergency services to people with acute mental health needs located in the Dunedin Hospital (201 Great King St, Ground floor, Psychiatric Services Building; Freephone: 0800 46 78 46 and ask for EPS).

All the best with your mobile mindfulness practice,

Kind regards,

Dr. Tess Patterson (Principal Investigator; tess.patterson@otago.ac.nz) and the Mobile Mindfulness Team

HEADSPACE FOLLOW UP EMAIL

Subject line: Mobile Mindfulness Meditation – Research study

Kia ora,

You are half way through your complimentary trial of Headspace! We hope the mobile mindfulness practice is going well. Don't forget, if you have missed a couple of days of mindfulness that is ok! Pick it up again if and when you can.

Here is the link to your next survey. Please remember that even if you are no longer interested in the app-based portion of this study, we would really appreciate it if you could complete this survey (approx. 15 minutes, a.k.a. a scientifically perfect amount of time to take a study break! http://time.com/3518053/perfect-break/). By completing this survey you are helping us to better understand both mental health and mobile health interventions.

POST HEADSPACE SURVEY LINK

All the best with your mobile mindfulness practice,

Kind regards,

Dr. Tess Patterson (Principal Investigator; tess.patterson@otago.ac.nz) and the Mobile Mindfulness Team

Remember, if you have any questions about the app, please check out the FAQ's here https://www.headspace.com/faqs if you have any technical issues that aren't resolved using the FAQs, please contact headspace here https://www.headspace.com/contact-us

We hope you enjoy using Headspace, however, we would like to remind you that if mobile mindfulness meditation is not right for you in any way or makes you feel increasingly distressed, please cease practice. You are welcome to resume practice at a later stage if you wish to do so.

If you experience distressing feelings or thoughts related to mindfulness app use and these distressing feelings or thoughts are ongoing or are severe enough that you feel concerned about what you experienced, please cease mindfulness meditation and contact Dr. Kim Ma'ia'i or Dr. Jubilee Rajiah. To contact Dr. Ma'ia'i or Dr. Rajiah, please call Student Health Services reception at 03 479 8212 or 0800 479 821 and ask to speak with either Dr. Ma'ia'i or Dr. Rajiah. Dr. Ma'ia'i and Dr. Rajiah are experienced clinicians who will conduct an over the phone clinical assessment in order to determine the appropriate response to your experience. If it is outside of Student Health Services' normal hours we would request that you contact Emergency Psychiatric Services and tell them about your experiences. Emergency Psychiatric Service is a mobile 24-hour, 7-day a week service providing emergency services to people with acute mental health needs located in the Dunedin Hospital (201 Great King St, Ground floor, Psychiatric Services Building; Freephone: 0800 46 78 46 and ask for EPS).

REMINDER EMAIL

Subject line: Mobile Mindfulness Meditation – Research study REMINDER – PLEASE COMPLETE SURVEY ASAP

Hi there,

This is just a reminder to please complete this survey ASAP – SURVEY LINK

Even if you are no longer interested in the app-based portion of this study, we would really appreciate it if you could complete this survey (approx. 15 minutes, a.k.a. a scientifically perfect amount of time to take a study break! http://time.com/3518053/perfect-break/). By

completing this survey you are helping us to better understand both mental health and mobile health interventions.

All the best,

Dr. Tess Patterson (Principal Investigator; tess.patterson@otago.ac.nz) and the Mobile Mindfulness Team

Supplement 4.4. Trial Safety Protocol

Safety Protocol
Student Researcher, Jayde Flett, will liaise with the following:
• Research team – Dr. Tess Patterson, Prof. Harlene Hayne, Dr. Tamlin Conner, and Dr. Kim Ma'ia'i – for clinical and technical research design, and support. Biostatistician, Andrew Gray, as point of statistical support.
•Counselling Team via Drs. Kim Ma'ia'i, Jodie Black, Mark Chignall, and Jubilee Rajiah – for all issues related to recruitment, clinicians, and adverse events.
•Headspace – Brad Sanderson [brad@headspace.com] - for all technical application issues
•Dept. of Psychology – Programmer – Hadyn Youens – for all technical data collection issues

Topics to be discussed and approved by those involved.
•Trial management of recruitment through the counselling team
•Data management, analysis, security, and quality assurance
•Monitoring the safety of the participants

Trial Management

- Primary liaison – Jayde Flett – will be the contact person for all involved parties.
- Recruitment through Student Health Services – Counselling Service Team
- Projected timetable – enrolment to begin at start of Semester 2, July 2016 and will continue until December 2017 (approximately 18 months). This recruitment period is based on discussions with the Counselling Team Research Advisor, Jodie Black, Student Health Services, who has indicated the number of *new* students who access their service per week (i.e., on average 18 students per week) which indicates that there will be approximately 810 students available for potential recruitment over the 18 month time period (working on an average 15 week semester including examination times).
- Targeted population distribution – inclusive, meet eligibility criteria, distressed students

Data Management, Analysis, Security, and Quality Assurance

- Data acquisition and transmission – data acquired through online surveys. Input by participants and clinician. Stored in password protected location in Dept. of Psychology servers.
- Quality assurance – surveys to be piloted late Semester 1 to ensure all data is coded correctly (procedures in place to ensure the validity and integrity of the data).
- Preliminary data analysis to occur at monthly intervals to guarantee the accuracy and completeness of the data, during data collection, entry, transmission, and analysis.
- Primary data analysis to occur at end of university year data collection to assess effectiveness of trial.

Trial Safety

- All participants will be made aware by their clinician that if they deem their psychological state to be deteriorating they are to contact Student Health Services or Emergency Psychiatric Services (i.e., standard practice at Student Health Counselling Service).
- All participants will be made aware that if they experience distressing feeling related to the mobile mindfulness app they are able to cease using the app. Further, if participants experience severe or ongoing distress in relation to the app use or are concerned about their response to the app use (i.e., adverse experience/ event), participants are to contact Dr Ma'ia'i, or Dr Rajiah. Dr Ma'ia'i/ Dr Rajiah will conduct a clinical assessment in order to determine appropriate response to the adverse event experienced. Dr Ma'ia'i/ Dr Rajiah will report the occurrence, severity, and management of the adverse event to the research team within a 48 hour time period. If 2+ participants report adverse experiences with the app, the research team will meet to decide whether the trial will be terminated; if so, all participants and clinicians will be contacted immediately.
- All participants will remain under the clinical care of a treating clinician as part of their normal care and receive treatment-as-usual throughout their time at Student Health Services' – Counselling Service.
- All participants will be made aware that they may terminate their use of Headspace if they deem it to be having a negative effect on their well-being and that this termination will not in any way affect the provision of care at Student Health Services' – Counselling Service.

- All participants will be asked to continue completing surveys of their psychological health outcomes during their treatment even if they terminate use of Headspace.
- Although unlikely, clinicians will have the right to recommend that their client's terminate use of Headspace if they deem it to be having a negative effect on their well-being (i.e., in the case of a participant choosing to discuss their use of the app as negative and as part of the clinical session). This will come at no disadvantage to the client or clinician.

Supplement 4.5. Memorandum of Understanding available on request

CHAPTER 5: SUPPLEMENTS

Supplements for Chapter 5 include:

S 5.1 Per protocol: Equivalency of baseline characteristics and app use characteristics by condition

S 5.2. Participant academic achievement

S 5.3. Per protocol: App use (continuous) as a predictor of Intervention participants' mental health

S 5.4. Per protocol: App use (continuous) as a predictor of Waitlist participants' mental health

S 5.5. ITT + PP: App use (categorical) as a predictor of waitlist participants' mental health at Time 3

S 5.6. ITT + PP: App use (categorical) as a predictor of intervention participants mental health at Time 3

Supplementary Table 5.1.

Equivalency of baseline characteristics (Time 1: top rows) and app use characteristics (bottom rows) overall and by condition.

	Per Protocol			One-way ANOVA (Chi-square)		
	Overall	Intervention	Waitlist	*F* (X^2)	*df*	*p* (Sig)
	M (SD)	*M* (SD)	*M* (SD)			
Age (years)	17.87 (.46)	17.90 (.45)	17.85 (.48)	.68	1, 193	.411
Gender (female; *n* %)	138 (70.8)	67 (73.6)	71 (68.3)	.67	1	.412
Ethnicity (NZ European; *n* %)	160 (82.0)	81 (89.0)	92 (88.5)	.76	1	.383
Distress [1]	19.72 (5.40)	20.26 (5.37)	19.25 (5.42)	1.72	1, 193	.192
College adjustment	82.99 (15.98)	81.46 (15.68)	84.33 (16.2)	1.56	1, 193	.213
Positive affect	31.48 (5.34)	30.82 (5.17)	32.05 (5.44)	2.57	1, 193	.110
Negative affect	35.90 (10.30)	36.82 (9.67)	35.10 (10.80)	1.37	1, 193	.243
Homesickness	24.28 (6.96)	24.45 (7.31)	24.13 (6.67)	.11	1, 193	.745
Resilience	3.37 (.72)	3.30 (.77)	3.44 (.68)	1.99	1, 193	.160
Self-efficacy	29.97 (4.46)	30.03 (4.26)	29.97 (4.61)	.07	1, 193	.789
Mindfulness	30.71 (4.96)	30.34 (4.77)	31.16 (5.07)	1.30	1, 193	.255
Practicing ≥ 1 day (*n* %)	123 (63.1)	69 (75.8)	54 (51.9)	11.90	1	.001
Practicing ≥ 1 week (*n* %)	88 (45.1)	48 (52.7)	40 (38.5)	4.00	1	.046
Practicing ≥ 4 weeks (*n* %)	63 (32.3)	36 (39.6)	27 (26.0)	4.10	1	.043
Practicing ≥ 6 weeks (*n* %)	49 (25.1)	29 (31.9)	20 (19.2)	4.12	1	.042
Practicing ≥ 3 months (*n* %)	15 (7.7)	10 (11.0)	5 (4.8)	2.61	1	1.06
Practice duration (days)	23.28 (31.67)	28.43 (33.51)	18.78 (29.4)	4.59	1, 193	.033
n meditation sessions	8.43 (15.09)	10.16 (17.04)	6.91 (13.06)	2.27	1, 193	.134
Minutes meditated 4 weeks	40.33 (64.46)	51.81 (74.07)	30.29 (53.05)	5.54	1, 193	.020
Minutes meditated overall	79.39 (166.85)	102.09 (177.86)	59.54 (154.73)	3.19	1, 193	.076
Expectations (Time 1)	3.11 (.55)	3.14 (.60)	3.08 (.05)	.59	1, 193	.443
Expectations (Time 2)	2.91 (.64)	2.76 (.73)	3.04 (.52)	10.03	1, 193	.002
Expectations (Time 3)	2.85 (.70)	2.79 (.78)	2.90 (.63)	.528	1, 193	.469

Note: *M* = Mean, *SD* = Standard deviation. [1] Distress from the K10 was the preregistered primary outcome variable.

Supplementary Table 5.2.

PP: Descriptive statistics of academic achievement for all participants included in the Primary Analyses

	Overall				Intervention (*n* = 91)				Waitlist (*n* = 104)				One Way ANOVA		
Outcome	*M*	*SD*	Min	Max	*M*	*SD*	Min	Max	*M*	*SD*	Min	Max	*F*	*df*	*p*
Academic achievement	80.33	10.57	47	98	80.57	10.39	50	98	80.12	10.77	47	95	.09	1, 193	.770
Semester 1	80.10	11.75	35	99	80.39	11.67	30	99	79.84	11.88	40	97	.11	1, 193	.742
Semester 2	80.84	10.83	45	98	80.99	10.51	55	98	80.70	11.16	45	95	.04	1, 193	.851

Supplementary Table 5.3.

PP data: Mental health and academic outcomes from Time 1 to Time 3 were predicted using waitlist participants' objective app use. Time 0 outcome scores were controlled in all analyses.

	Time 3					
Outcome	Constant (SE)	Baseline of outcome (SE)	ß of App Use (SE)	Sig of App Use (2-tailed)	BCa 95% CI of App Use	R^2 (R^2 change attributed to App Use)
K10 Distress	17.60 (1.10)**	.48 (.18)*	.09 (.10)	.343	-.044, .312	.272 (.033)
College Adjustment	92.59 (2.91)**	.54 (.14)**	-.17 (.20)	.309	-.581, .406	.282 (.015)
Positive affect	30.13 (1.10)**	.45 (.17)*	-.02 (.12)	.871	-.339, .147	.129 (.001)
Negative affect	30.39 (2.07)**	.52 (.13)**	.10 (.11)	.295	-.114, .218	.274 (.011)
Homesickness	16.62 (1.09)**	.39 (.12)**	.13 (.09)	.096	-.058, .237	.270 (.063)*
Resilience	3.23 (.12)**	.65 (.13)**	.00 (.01)	.739	-.012, .021	.354 (.001)
Self-efficacy	29.91 (.87)**	.58 (.11)**	.08 (.04)	.051	-.006, .159	.340 (.043)†
Mindfulness	31.18 (.89)**	.77 (.18)**	-.04 (.06)	.435	-.154, .120	.375 (.007)
Academic achievement	84.47 (1.26)**	-	-.08 (.07)	.222	-.233, .063	-(.013)
Semester Two	85.06 (1.35)***	-	-.13 (.08)	.062	-.319, .032	-(.031)

Note: Bolded outcomes were registered primary outcome variables, † $p < .10$, * $p < .05$, ** $p < .01$, *** $p < .001$ denotes significance levels where otherwise unspecified.

Supplementary Table 5.4.

PP data: Mental health and academic outcomes from Time 1 to Time 2 (top rows), and from Time 1 to Time 3 (bottom rows) were predicted using intervention participants' objective app use. Time 0 outcome scores were controlled in all analyses.

	Time 2					
Outcome	Constant (SE)	Baseline of outcome (SE)	ß of App Use (SE)	Sig of App Use (2-tailed)	BCa 95% CI of App Use	R^2 (R^2 change attributed to app use)
K10 Distress	19.82 (.68)**	.74 (.12)**	-.07 (-.04)	.069	-.143, -.022	.407 (.030)*
College Adjustment	85.89 (2.03)**	.63 (.09)**	.12 (.16)	.349	-.050, .588	.338 (.014)
Positive affect	29.30 (.56)**	.57 (.11)**	-.01 (.04)	.801	-.058, .110	.307 (.001)
Negative affect	32.10 (1.28)**	.63 (.10)**	-.08 (.09)	.331	-.326, .020	.321 (.015)
Homesickness	22.12 (.88)**	.50(.09)**	-.06 (.05)	.158	-.202, -.014	.264 (.022)
Resilience	3.32 (.07)**	.71 (.07)**	.00 (.00)	.343	-.004, .013	.506 (.004)
Self-efficacy	29.57 (.44)**	.64 (.10)**	.05 (.02)	.024	.000, .106	.383 (.038)*
Mindfulness	30.49 (.52)**	.60 (.09)**	.05 (.04)	.133	-.028, .125	.357 (.030)*
Academic achievement	81.42 (1.29)**	-	-.08 (.09)	.317	-.205, .170	- (.019)
Semester One	80.70 (1.34)**	-	-.03 (.09)	.696	-.151, .236	- (.002)
	Time 3					
K10 Distress	18.71 (.88)**	.47 (.13)**	-.08 (.03)	.003	-.148, -.043	.264 (.090)*
College Adjustment	90.48 (2.93)**	.46 (.16)**	.28 (.17)	.014	-.082, .638	.253 (.092)*
Positive affect	30.47 (1.00)**	.41(.14)**	.03 (.06)	.406	-.100, .124	.178 (.009)
Negative affect	31.17 (1.89)**	.46 (.16)**	-.18 (.09)	.010	-.366, .091	.224 (.093)*
Homesickness	19.17 (1.43)**	.35 (.15)*	-.11 (.08)	.066	-.314, -.040	.220 (.075)†
Resilience	3.34 (.14)**	.63 (.14)**	.01 (.01)	.444	-.005, .039	.390 (.013)
Self-efficacy	31.36 (.67)**	.64 (.18)**	.03 (.04)	.271	-.071, .094	.277 (.018)
Mindfulness	31.17 (.92)**	.74 (.16)**	.08 (.05)	.035	-.024, .170	.429 (.060)†
Academic achievement	84.40 (1.97)**	-	-.20 (.15)	.077	-.293, .345	- (.131)*
Semester Two	84.99 (1.76)**	-	-.17 (.12)	.050	-.250, .240	- (.130)*

Note: Bolded outcomes were registered primary outcome variables, † $p < .10$, * $p < .05$, ** $p < .01$, *** $p < .001$ denotes significance levels where otherwise unspecified.

Supplementary Table 5.5.

Mental health at Time 3 (intention-to-treat: top rows; per-protocol: bottom rows) was predicted using waitlist participants' objective app use categorically coded into No use (0-3 meditations), Low use (4-8 meditations), and Moderate use (9+ meditations). Time 1 outcomes were controlled in all analyses.

Outcome	(No use) Constant (SE)	Baseline of outcome (SE)	(No use vs.) Low use ß (SE)	Sig (2-tailed)	Sig' (2-tailed)	(No use vs.) Moderate use ß (SE)	Sig (2-tailed)	Sig' (2-tailed)	(Low use) Constant (SE)	(Low use vs.) Moderate use ß (SE)	Sig (2-tailed)	Sig' (2-tailed)	R^2 (R^2 change)
Distress	18.05 (.53)***	.24 (.08)**	1.01 (1.41)	.474	1.00	.30 (.95)	.755	1.00	19.06 (1.32)***	-.71 (1.52)	.640	1.00	.11 (.11)
College adjustment	94.00 (1.39)***	.26 (.07)***	-3.23 (3.84)	.400	1.00	-.42 (2.58)	.872	1.00	90.76 (3.60)***	2.82 (4.20)	.503	1.00	.13 (.01)
Positive affect	30.72 (.59)***	.26 (.09)**	-1.20 (1.66)	.468	1.00	-.10 (1.10)	.929	1.00	29.52 (1.53)***	1.10 (1.78)	.535	1.00	.08 (.01)
Negative affect	29.68 (.94)***	.24 (.07)***	2.29 (2.56)	.372	1.00	-.21 (1.74)	.902	1.00	31.98 (2.38)***	-2.51 (2.79)	.369	1.00	.11 (.01)
Homesickness	16.96 (.58)***	.18 (.07)**	1.26 (1.61)	.435	1.00	1.02 (1.03)	.322	1.00	18.22 (1.50)***	-.23 (1.75)	.893	1.00	.09 (.02)
Resilience	3.41 (.07)***	.37 (.08)***	-.26 (.19)	.157	1.00	.08 (.12)	.480	1.00	3.15 (.18)***	.35 (.21)	.092	1.00	.22 (.03)
Self-efficacy	30.23 (.43)***	.33 (.07)***	-1.24 (1.14)	.277	1.00	1.12 (.73)	.126	1.00	28.99 (1.05)***	2.36 (1.23)	.055	1.00	.23 (.03)
Mindfulness	31.99 (.52)***	.32 (.08)***	-3.37 (1.39)	.015	.645	-.27 (.94)	.774	1.00	28.61 (1.33)***	3.10 (1.54)	.044	1.00	.18 (.05)
Distress	17.60 (1.09)**	.53 (.19)*	2.79 (2.10)	.166	1.00	1.45 (1.58)	.395	1.00	20.39 (2.20)**	-1.34 (2.24)	.542	1.00	.263(.024)
College adjustment	92.45 (3.21)**	.58 (.13)**	-8.26 (9.01)	.361	1.00	-1.91 (4.28)	.666	1.00	84.19 (8.73)**	6.35 (9.86)	.517	1.00	.287 (.020)
Positive affect	30.47 (1.05)**	.50 (.15)**	-2.96 (4.37)	.496	1.00	-.49 (1.76)	.798	1.00	27.51 (4.36)**	2.46 (4.46)	.599	1.00	.144 (.015)
Negative affect	30.73 (2.38)**	.54 (.14)**	5.35 (4.76)	.238	1.00	.12 (2.91)	.969	1.00	36.08 (4.49)**	-5.23 (4.64)	.230	1.00	.285 (.022)
Homesickness	16.60 (1.08)**	.45 (.13)**	3.33 (2.90)	.213	1.00	2.43 (1.61)	.140	1.00	19.93 (2.56)**	-.90 (2.94)	.761	1.00	.251 (.044)
Resilience	3.29 (.13)**	.61 (.12)**	-.33 (.27)	.212	1.00	.20 (.17)	.223	1.00	2.96 (.23)**	.54 (.26)	.037	1.00	.404(.051)
Self-efficacy	30.02 (1.15)**	.60 (.11)**	-1.46 (1.57)	.366	1.00	1.89 (1.24)	.155	1.00	28.56 (1.09)**	3.35 (1.14)	.010	.440	.357 (.060)
Mindfulness	32.14 (.91)**	.82 (.16)**	-7.41 (2.63)	.006	.276	-1.19 (1.25)	.360	1.00	24.73 (2.62)**	6.22 (2.57)	.015	.629	.507 (.139)**

Note: † $p < .10$, * $p < .05$, ** $p < .01$, *** $p < .001$ denotes unadjusted significance levels where otherwise unspecified. Sig' (2-tailed) = significance values using the Holm-Bonferroni sequential correction

Supplementary Table 5.6.

Mental health at Time 3 (intention-to-treat: top rows; per-protocol: bottom rows) was predicted using intervention participants' objective app use categorically coded into No use (0-3 meditations), Low use (4-8 meditations), and Moderate use (9+ meditations). Time 1 outcome scores were controlled in all analyses.

Outcome	(No use) Constant (SE)	Baseline of outcome (SE)	(No use vs.) Low use ß (SE)	Sig (2-tailed)	(No use vs.) Moderate use ß (SE)	Sig (2-tailed)	(Low use) Constant (SE)	(Low use vs.) Moderate use ß (SE)	Sig (2-tailed)	R^2 (R^2 change)
Distress	18.54 (.44)***	.13 (.07) †	1.31 (1.03)	.205	-1.61 (.78)	.040	19.85 (.91)***	-2.92 (1.16)	.012	.12 (.08)*
College adjustment	92.24 (1.39)***	.16 (.06)*	-2.18 (3.17)	.492	4.51 (2.32)	.052	90.06 (2.85)***	6.69 (3.47)	.054	.10 (.05) †
Positive affect	30.59 (.56)***	.18 (.08)*	-.27 (1.19)	.821	.31 (.90)	.732	30.32 (1.04)***	.58 (1.26)	.647	.07 (.01)
Negative affect	30.23 (.88)***	.14 (.07)*	1.57 (2.05)	.444	-2.50 (1.51)	.097	31.80 (1.84)***	-4.07 (2.25)	.071	.08 (.04)
Homesickness	18.34 (.61)***	.15 (.07)*	.60 (1.42)	.671	-2.32 (1.08)	.032	18.94 (1.31)***	-2.92 (1.60)	.069	.11 (.06) †
Resilience	3.34 (.07)***	.24 (.08)**	-.03 (.16)	.857	.18 (.12)	.139	3.31 (.14)***	.21 (.18)	.232	.14 (.03)
Self-efficacy	30.69 (.43)***	.12 (.07)*	-.59 (.92)	.520	.88 (.73)	.234	30.10 (.84)***	1.47 (1.08)	.175	.08 (.03)
Mindfulness	31.27 (.53)***	.29 (.08)***	-.48 (1.18)	.686	2.00 (.86)	.021	30.79 (1.05)	2.48 (1.28)	.053	.19 (.06)*
Distress	18.03 (1.08)**	.44 (.12)**	3.72 (2.52)	.132	-2.19 (1.37)	.131	21.75 (2.25)**	-5.91 (2.47)	.020	.346 (.172)*
College adjustment	89.04 (3.60)**	.39 (.17)*	1.38 (6.71)	.837	10.67 (5.50)	.067	90.42 (5.62)**	9.28 (6.77)	.159	.245 (.084)
Positive affect	30.54 (1.30)**	.40 (.14)**	.20 (2.53)	.930	.51 (1.80)	.781	30.75 (2.16)**	.31 (2.56)	.893	.171 (.002)
Negative affect	31.47 (2.46)**	.39 (.19)*	.01 (4.85)	.998	-5.68 (3.47)	.124	31.48 (4.25)**	-5.69 (5.10)	.244	.197 (.067)
Homesickness	20.83 (1.90)**	.27 (.14)*	-1.66 (2.36)	.472	-6.08 (2.27)	.011	19.17 (1.53)**	-4.42 (1.92)	.031	.292 (.147)*
Resilience	3.17 (.17)**	.59 (.12)**	.29 (.31)	.348	.40 (.21)	.069	3.47 (.26)**	.11 (.29)	.697	.431 (.054)
Self-efficacy	31.86 (.81)**	.55 (.17)**	-1.43 (1.18)	.226	.27 (1.21)	.838	30.43 (.84)**	1.70 (1.34)	.212	.280 (.022)
Mindfulness	30.98 (1.08)**	.62 (.14)**	-.58 (2.28)	.798	2.82 (1.44)	.065	30.41 (2.01)**	3.40 (2.27)	.153	.439 (.070)

Note: † $p < .10$, * $p < .05$, ** $p < .01$, *** $p < .001$ denotes significance levels where otherwise unspecified.